No.

TOWN OF WALLINGFORD, Plaintiff, vs. PURDUE PHARMA L.P., d/b/a PURDUE PHARMA (DELAWARE) LIMITED PARTNERSHIP; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC f/k/a ACTAVIS PLC; ACTAVIS, INC. f/k/a WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; MALLINCKRODT PLC; MALLINCKRODT LLC; and INSYS THERAPEUTICS, INC., Manufacturer Defendants, - and – MCKESSON CORPORATION, CARDINAL HEALTH, INC., and AMERISOURCE BERGEN DRUG CORPORATION, Distributor Defendants, - and – JOHN KAPOOR, Individual Defendant.	SUPERIOR COURT JUDICIAL DISTRICT OF NEW HAVEN AT NEW HAVEN APRIL 10, 2018

TABLE OF CONTENTS

COMPLAINT

Plaintiff, Town of Wallingford, Connecticut, with offices located at 45 South Main Street Wallingford, CT 06492, alleges as follows:

I. PRELIMINARY STATEMENT

1. Many communities in the United States, including the Town of Wallingford, Connecticut ("Plaintiff," "Town," and "Town of Wallingford"), are currently experiencing a stark increase in the number of its residents who have become addicted to prescription opioids and heroin, and a stark increase in opioid overdoses. Prescription opioids are now known to be the "gateway" drug to heroin; approximately 80% of current heroin users got their start with prescription opioids.[1] Unlike any other epidemic, the opioid epidemic is largely man-made and is being fueled by the continuing unlawful conduct of the defendant pharmaceutical manufacturers ("Manufacturer Defendants") and pharmaceutical wholesale distributors ("Distributor Defendants").

1. A pharmaceutical manufacturer should never place its desire for profits above the health and well-being of its customers. Drug manufacturers have a legal duty to ensure their products are accompanied by full and accurate instructions and warnings to guide prescribing doctors and other healthcare providers in making treatment decisions. A pharmaceutical manufacturer has a legal duty to tell the truth when marketing its drugs and to ensure that its marketing claims are supported by science and medical evidence. A pharmaceutical distributor of controlled substances has a legal duty to conduct its business lawfully and carefully and in a manner that does not irresponsibly and unreasonably saturate the market with opioids.

[1] *Prescription Opioids and Heroin*, National Institute on Drug Abuse (Dec. 16, 2015), https://www.drugabuse.gov/publications/research-reports/prescription-opioids-heroin.

Executives of a pharmaceutical company, such as Individual Defendant, have a legal obligation to ensure that their company conducts itself in a manner compliant with the law that is designed to protect rather than harm patients. Defendants broke these simple rules.

2. Manufacturer Defendants (Purdue Pharma L.P., d/b/a Purdue Pharma (Delaware) Limited Partnership; Purdue Pharma Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Allergan plc f/k/a Actavis plc; Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.; Watson Laboratories, Inc.; Actavis LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; and Insys Therapeutics, Inc.) knew that opioids were effective treatments for short-term use such as post-surgical and trauma-related pain, and for end-of-life care. They also knew that prescription opioids were addictive and subject to abuse, particularly when used long-term for chronic non-cancer pain, and should be used, if at all, as a last resort. Defendants also knew that, with prolonged use, the effectiveness of opioids decreases, requiring dosage increases to reduce pain, thereby increasing the risk of significant side effects and addiction.

3. Prior to the mid-1990s, medical orthodoxy rejected the use of opioids as an accepted modality for the long-term treatment for chronic pain. The U.S. Food and Drug Administration ("FDA") has expressly recognized that there have been no long-term studies demonstrating the safety and efficacy of opioids for long-term use.[2]

[2] Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Evaluation & Research, to Andrew Kolodny, M.D., President, Physicians for Responsible Opioid Prescribing, Re: Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

4. In order to expand their market for opioids and realize blockbuster profits, Manufacturer Defendants needed to create a fundamental change in medical orthodoxy and public perception that would make opioids permissible and even the preferred treatment modality, not just for acute and palliative care, but also for long-term treatment of everyday aches and pains, like lower back pain, arthritis, headaches and sports injuries.

5. Since the mid-1990s, the Manufacturer Defendants, led by Purdue Pharma, have engaged in a scheme to boost sales for their prescription opioid products by upending medical orthodoxy and popular belief regarding the safety and efficacy of long-term opiate use. Defendants accomplished this reversal by falsely promoting their highly dangerous products for the use of chronic pain and knowingly, recklessly and negligently, and with wanton disregard for the public health, denying or trivializing the risk of addiction.

6. In furtherance of their scheme, each Manufacturer Defendant expended millions of dollars and used the following unethical and unlawful methods to disseminate misinformation regarding the safety and efficacy of long-term opioid use for pain management treatment, including:

(a) paying off doctors called Key Opinion Leaders ("KOLs") to give speeches and write misleading studies advocating the advantages of prescription opioids, and to present deceptive continuing medical education programs ("CMEs") promulgating the message to fellow physicians that opioids were an approved long-term treatment;

(b) promoting the use of opioids for chronic pain through sales representatives, also called "detailers," whose jobs involved visiting individual physicians and their staff in their offices and setting up small group speaker programs. By establishing close relationships with doctors, the sales representatives

were able to disseminate their misrepresentations in targeted one-on-one settings that allowed them to address and dispel individual prescribers' reservations about prescribing opioids for chronic pain. Representatives were trained on techniques to build these relationships, with Manufacturer Defendant Actavis even rolling out an "Own the Nurse" kit as a "door opener" to time with doctors. Using the sales representatives as "foot soldiers" in the misinformation campaign, the Manufacturer Defendants were able to address individual prescribers' concerns about prescribing opioids for chronic pain, and to push higher doses of the opioids, thereby driving up revenue.

(c) twisting scientific literature; most notably, transforming a five-sentence letter written to the NEW ENGLAND JOURNAL OF MEDICINE in 1980 by Doctor Hershel Jick and his graduate assistant, Jane Porter ("Porter/Jick Letter"), regarding the relative safety of short-term opioid use by patients in a medical setting, into a false assertion (cited more than 600 times) that long-term opioid use in a non-medical setting has been proven to be "safe" and non-addictive;

(d) infiltrating medical societies and CMEs with the false information that chronic pain could and should be safely treated with prescription opioids;

(e) using non-branded advertisements (that promote opioids generally, rather than any particular brand), which advertisements are not regulated by the FDA, to falsely promise relief from pain with no harmful side-effects from opioids;

(f) providing front groups with tens of millions of dollars and giving them official-sounding names, such as "American Pain Foundation," to disseminate the

falsehood that addiction is a very minor and easily handled risk of prescription opioids; and

(g) influencing consumers and the lay public through magazine articles, newspaper stories, TV programs, etc., featuring KOLs and front groups regarding the falsely described advantages of opioids for chronic pain, with the specific intention and effect of recruiting patients to demand opioids from their treating physicians.

7. Defendants' actions are not permitted or excused by the fact that the FDA did not require that their products' labels specifically exclude the use of opioids for chronic pain. Accurate content on a label of a pharmaceutical product is squarely the responsibility of the manufacturer. The FDA approval of their drugs for narrowly defined applications did not entitle Defendants to misrepresent the risks, benefits, or superiority of opioids. In fact, unlike any other prescription drugs that may have been marketed unlawfully in the past, opioids are highly addictive controlled substances. Thus, Manufacturer Defendants deceptively engaged – and in many instances profoundly harmed – a patient base that by definition was not able, biologically, to turn away from the drugs. These drugs would never have been prescribed in the first place, but for the Manufacturer Defendants' unlawful scheme.

8. Defendants' causal role is also not broken by the involvement of legitimate doctors writing opioid prescriptions for their patients. Defendants' ubiquitous marketing efforts and their deceptive messages tainted virtually every information source doctors could rely on and prevented these doctors from making informed treatment decisions. Defendants targeted not only pain specialists, but also primary care physicians, nurse practitioners, physician assistants, and other non-pain specialists who were even less likely to be able to assess the companies' misleading statements.

9. To the huge detriment of the health of Americans, Connecticut residents, and residents of the Town of Wallingford, and to the Town of Wallingford itself, the scheme of the Manufacturer Defendants (which was well-funded, well-organized, and pervasive) was extremely successful. In just a few years, the Manufacturer Defendants managed to jettison decades of well-established and sound medical orthodoxy holding that prescription opioids are far too addictive and potentially debilitating to be used to treat chronic pain. Manufacturer Defendants individually, and working together through their front groups and KOLs, persuaded doctors, patients, and even hospitals that what they had long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was no longer true, and that the opposite, that the compassionate treatment of pain ***required*** opioids, the most superior pain management protocol, was the new truth.

10. For example, the Manufacturer Defendants, acting through one of their front groups, the American Pain Society, successfully introduced "Pain as the Fifth Vital Sign" factor, which, along with respiration rate, body temperature, blood pressure, and pulse rate, is now considered to be a "vital sign" upon which doctors assess patients.[3] The Pain as a Fifth Vital Sign campaign was adopted by the Veterans Administration and the Joint Commission (responsible for accreditation of hospitals), both of whom had extensive financial relationships with Purdue at the time of the roll-out of the campaign.

[3] *See* Natalia E. Morone, M.D. & Deborah K. Weiner, M.D., *Pain as the Fifth Vital Sign: Exposing the Vital Need for Pain Education*, 35(11) CLIN. THER. 1728, 1729 (2013). In 2016, the American Medical Association recommended removing pain as the fifth vital sign. *See* Joyce Frieden, *Remove Pain as 5th Vital Sign, AMA Urged*, MEDPAGE TODAY (June 13, 2016), https://www.medpagetoday.com/meetingcoverage/ama/58486 ("Just as we now know earth [is] not flat, we know that pain is not a vital sign.").

11. The profits of the Manufacturer Defendants skyrocketed. Opioid sales have steadily risen, from $3.8 billion in 2000, to $8 billion in 2010, to $9.6 billion in 2015. Purdue has earned more than ***$35 billion*** in opioid profits since 1996, including more than $3 billion in 2015 (from $800 million in 2006). Purdue's OxyContin sales rose from $45 million in 1996 to $3.1 billion in 2010. Endo Pharmaceuticals has gained a tremendous amount of revenue from opioid sales as well, reaping over $1 billion from Opana ER alone in 2010, and again in 2013.

12. Three Distributor Defendants, McKesson Corporation ("McKesson"), Cardinal Health Inc. ("Cardinal"), and AmerisourceBergen Drug Corporation ("ABC") dominate 85-90% of the market share of prescription opioid distribution in the U.S.[4]

13. The 1970 Controlled Substances Act ("CSA"), 21 U.S.C. §§801 *et seq.*, and corollary state law Conn. Gen. Stat. §21a-70(b), requires wholesale distributors of "controlled substances" (all the prescription opioids involved in the opioid epidemic and listed in Tables 1-7, *infra*, are either Schedule II or III controlled substances), to register with the U.S. Drug Enforcement Administration ("DEA") to be approved as a vendor of controlled substances. 21 U.S.C. §§821-30.

14. In order to get and retain the coveted registration (without which a wholesale distributor cannot lawfully sell any prescription opioids in the United States), the wholesale distributor has a statutory duty that mirrors its common law duty to conduct its business of distributing dangerous drugs in a reasonable and safe manner. Included among these obligations are the duties "to report to [the] DEA suspicious orders for controlled substances and to take other precautions to ensure that those medications would not be diverted into illegal channels."

[4] Adam J. Fein, Ph.D., *2016 MDM Market Leaders/Top Pharmaceutical Distributors*, MDM (2017), https://www.mdm.com/2016-top-pharmaceuticals-distributors.

Masters Pharm., Inc. v. DEA, 861 F.3d 206, 211-12 (D.C. Cir. 2017); 21 C.F.R. §1301.77. Conn. Gen. Stat. §21a-70(e) requires the wholesale distributor of prescription drugs to "operate in compliance with applicable federal, state and local statutes, regulations and ordinances, including any applicable laws concerning controlled substances, drug product salvaging or reprocessing."

15. Each Distributor Defendant utterly failed to discharge its statutory obligations to maintain and monitor a closed chain of distribution, and to detect, report, inspect, and halt suspicious orders so as to prevent the misuse or black market diversion of controlled substances, as required under state and federal law. The direct and foreseeable result of the Distributor Defendants' unlawful conduct is that many communities, including Wallingford, Connecticut, have been flooded with an excess supply of pharmaceutical opioids.

16. Each Distributor Defendant has been investigated and fined by the DEA for failing to:

(a) operate its mandatory internal oversight system in good faith;

(b) report suspicious orders to the DEA; and

(c) halt the shipment of "suspicious orders for controlled substances" when they were discovered.

17. McKesson, the largest wholesale distributor in the United States, agreed on January 17, 2017 to pay a $150 million fine to the U.S. Department of Justice ("DOJ") for its violations of the CSA.[5]

[5] *See* Justice News, DOJ, Office of Public Affairs (Jan. 17, 2017), *McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs*, https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

18. In late December 2016, Cardinal agreed to a $34 million fine to "resolve allegations that [it] failed to report to the DEA suspicious orders of Class II [powerful narcotics] by pharmacies located in Central Florida and Maryland."[6] This is the second settlement in less than a decade in which Cardinal has agreed to allegations by the federal government that it failed to report suspicious opioid orders.

19. Cardinal Health Inc. settled a lawsuit initiated by the State of West Virginia for $20 million, which alleged violations of the CSA that are similar to its violations in the State of Connecticut. *See State of W. Va. v. AmerisourceBergen Drug Corp.*, No. 12-C-141 (W. Va. Cir. Ct., Boone Cty.). AmerisourceBergen Drug Corporation also agreed to pay West Virginia $16 million for settlement of the same litigation. *See id.*

20. The explosion in opioid use and abuse, along with the corresponding explosion in profits for the Defendants, was not due to a medical breakthrough in pain treatment. Instead, it was due in substantial part – as the National Institutes of Health ("NIH") recognizes – to the "aggressive marketing" of Defendants. The NIH stated:

> Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and aggressive marketing by pharmaceutical companies.[7]

---

[6] *See* DOJ, U.S. Attorney's Office, Middle District of Florida (Dec. 23, 2016), *United States Reaches $34 Million Settlement With Cardinal Health For Civil Penalties Under The Controlled Substances Act*, https://www.justice.gov/usao-mdfl/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under.

[7] Nora D. Volkow, M.D., Senate Caucus on International Narcotics Control, NIH, *America's Addiction to Opioids: Heroin and Prescription Drug Abuse* (May 14, 2014). Available at http://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse (accessed February 26, 2018).

21. Over the past two decades, as the sales of opioids increased, so too did deaths and hospitalizations caused by opioids.[8]

22. Starting in or about 1996 – coinciding with a rapid increase in prescription opioid use for medical purposes as more fully set forth, *infra* – the United States has experienced an opioid epidemic which has been characterized as the worst drug epidemic in its history. An epidemic is defined as a sharp increase in the prevalence of a disease (or diseases) within a discreet period of time.[9] The principal disease associated with the opioid epidemic is opioid addiction, sometimes referred to as "opioid use disorder" or "opioid abuse or dependence."

23. The 2016 Guidelines issued by the Centers for Disease Control and Prevention ("CDC"), *Guideline for Prescribing Opioids for Chronic Pain* (the "2016 CDC Guidelines"), is a peer-reviewed guideline that is based on scientific evidence. It has defined "opioid addiction," "opioid use disorder," and "opioid abuse or dependence" as a "problematic pattern of opioid use leading to clinically significant impairment or distress . . . manifested by specific criteria such as unsuccessful efforts to cut down or control use and use resulting in social problems and a failure to fulfill major role obligations at work, school, or home."[10]

---

[8] Andrew Kolodny, *et al.*, *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction.*, ANNU. REV. PUBLIC HEALTH 2015. 36:559-74, http://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031914-122957 (accessed February 26, 2018).

[9] *Principles of Epidemiology in Public Health Practice, Third Edition: An Introduction to Applied Epidemiology and Biostatistics* (October 2016, updated May 2012), https://www.cdc.gov/ophss/csels/dsepd/ss1978/ss1978.pdf (accessed February 26, 2018).

[10] Deborah Dowell, M.D., *et al.*, CDC, *CDC Guidelines for Prescribing Opioids for Chronic Pain – United States, 2016*, March 18, 2016, at 2. The current diagnostic manual used by most behavioral health professionals, DSM-V, uses the term "opioid use disorder" to refer to and define what has in the past essentially been referred to as opioid addiction. In this Complaint, Plaintiff will generally use the term "addiction" to refer to opioid use disorder, opioid addiction, and opioid abuse or dependence, unless context dictates otherwise. These diagnoses are "different from tolerance (diminished response to a drug with repeated use) and physical

24. Opioid addiction, like other forms of addiction, is a chronic medical condition. It is treatable, but not curable. Unfortunately, for a variety of reasons, including a shortage of and limitations on resources, the presence of shame and stigma, and the presence of barriers to treatment, only a small percentage of patients who need treatment actually receive the right types of treatment and levels of care, in the right settings, for the right lengths of time. In the absence of proper treatment, the disease of addiction is progressive and frequently fatal. Even with optimal treatment for the optimal time at the optimal setting, opioid addiction tends to be a relapsing disease.

25. According to the U.S. Centers for Disease Control and Prevention ("CDC"), the opioid addiction has led to an epidemic in opioid overdoses, in turn leading to an increase in opioid fatalities. In the period 1994-2014, the CDC estimated that there were 165,000 overdose deaths in the United States associated with prescription opioid use.[11] Public health authorities estimate that, for every opioid overdose death, there are 30 non-fatal overdoses.[12] Thus, in the period 1999-2014, an estimated 5 million non-fatal opioid overdoses were also likely to have occurred. Of course, there are also untold tens of thousands of people who are seriously impaired in their ability to function in society by the disease of opioid addiction who do not necessarily experience overdoses.

---

dependence (adaptation to a drug that produces symptoms of withdrawal when the drug is stopped)." *Id.*

11 *Id.*, at 2, 18.

12 Andrea Hsu, *Hospitals Could Do More For Survivors Of Opioid Overdoses, Study Suggests*, NPR (Aug. 22, 2017), http://www.npr.org/sections/health-shots/2017/08/22/545115225/ hospitals-could-do-more-for-survivors-of-opioid-overdoses-study-suggests.

26. In 2016, the CDC acknowledged the existence of two opioid epidemics involving addiction and overdoses.[13]

27. The direct correlation between increases in sales of prescription opioids and opioid addiction and overdoses prompted the CDC and other public health authorities to conclude that the principal cause of both opioid epidemics was the unprecedented increase in use of prescription opioids.[14] The CDC gathered data relating to prescription opioid usage using sales of prescription opioids as a measure of prescription opioid usage, and correlated these data with data relating to admissions for treatment of opioid use disorders and overdose deaths. Using this data and analysis, the CDC and other researchers concluded that the daily use of prescription opioids to treat chronic pain has been the principal causative factor driving both epidemics in opioid addiction and overdoses.[15]

28. Public health authorities have also concluded that prescription opioid use is responsible not only for the addiction and overdose epidemics relating directly to prescription opioids, but also for the multi-year surge in non-prescription, illegal opioid use, including the use of heroin. As law enforcement and public health authorities and the medical profession have begun to limit the improper use of prescription opioids and for other reasons (including the high price of prescription opioids), which has reduced the supply of prescription opioids for legal use,

---

13 *CDC Guidelines*, March 18, 2016, at 3, 34, *supra* n.10; *accord* CDC Press Release, *CDC Launches Campaign to Help States Fight Prescription Opioid Epidemic* (Sept. 25, 2017) (hereinafter "CDC Press Release, Sept. 25, 2017"), https://www.cdc.gov/media/releases/2017/p0925-rx-awareness-campaigns.html (recognizing "opioid epidemic").

14 *Id.*, at 2.

15 *Id.*

many prescription opioid users suffering from opioid addiction have turned to heroin available on the black market.[16]

29. As the profits of the Defendants have increased year after year, so, too, have the numbers of substance abuse treatment admissions and overdose deaths in the State of Connecticut: the Connecticut Department of Mental Health and Addiction Services, Triennial State Substance Abuse Plan issued in 2016 states in pertinent part:

> Since the last plan was developed, one issue has heavily influenced many of the activities that state agencies are focused on. Connecticut has been in the grips of an opioid epidemic that has resulted in increasing numbers of overdose deaths across the state. At the same time, the substance abuse treatment system has seen substantial growth in treatment admissions that are directly related to opioid use. Overdose deaths and an increase in treatment admissions have rapidly intensified over the past three years. This issue has now become perhaps the single most important health concern we as a state are facing.[17]

The Town of Wallingford has been significantly impacted by the opioid crisis that is devastating Connecticut. According to data from the State's Office of the Chief Medical Examiner, the Town of Wallingford had only 3 opioid-related fatalities in 2012. By 2016 there were 15 such fatalities, constituting a 400% increase.

30. The catastrophic effects of each Manufacturer Defendant's unlawful deceptive marketing scheme and each Distributor Defendant's wanton, willful, reckless, and negligent

---

[16] Approximately 80% of individuals who begin using heroin made the transition from initial prescription opioids. *See* Andrew Kolodny, *et al*., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, ANNU. REV. PUBLIC HEALTH 2015. 36:559-574, at 560 (Jan. 12, 2015), http://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031914-122957; *accord The Mayor's Task Force to Combat the Opioid Epidemic in Philadelphia: Final Report and Recommendations*, City of Philadelphia, at 7 (May 19, 2017), http://dbhids.org/wp-content/uploads/2017/05/OTF_Report.pdf.

[17] State of Connecticut Dept. of Mental Health and Addiction Services Triennial State Substance Abuse Plan (2016) at 2, www.ct.gov/dmhas/lib/dmhas/publications/triennialreport2016.pdf.

violation of its statutory and common law gatekeeping role to ensure the supply of opioids into communities be maintained at safe levels, are only getting worse.

31. The Manufacturer Defendants' scheme of deception and the Distributor Defendants' failure to conduct their business in a lawful manner in compliance with state and federal statutory law and state common law have left the Town awash in opioids and strained the Town's resources to cope with the epidemics. In addition to the enormous costs to the Town's ability to provide traditional municipal services (*infra* at ¶¶346-66), the Town has also been forced to create and fund collaborative interventions to respond to the epidemics, such as: (1) The Opioid Action Team to improve local response from data sharing, collaboration, communication and coordination; (b) placing recovery coaches in the local hospital and recovery navigators in critical neighborhoods; (c) an "in reach" program for inmates with opioid use disorder to ease their transition from prison to the community; (d) a diversion program in the courts; (e) deploying a Community Care Team to those who have overdosed, etc. All such programs are well beyond the scope of what has ever been considered a municipal service.

32. Plaintiff, Town of Wallingford, brings this lawsuit to redress the violations of all the Defendants, to seek damages for the monies it has been forced to expend as a result of the Defendants' wrongful conduct. Moreover, Plaintiff seeks an order requiring the Defendants to abate the public nuisance created by Defendants.

33. Defendants' conduct has violated and continues to violate the Connecticut Unfair Trade Practices Act ("CUTPA"). Conn. Gen. Stat. §42-110a, *et seq*. Additionally, Defendants' conduct constitutes a common law public nuisance, common law fraud, negligent misrepresentation, negligence, and unjust enrichment.

34. To redress and enjoin Defendants' previous and continuous violations of the law, the Town of Wallingford brings this action seeking abatement, restitution, damages, disgorgement of unlawful profits, civil penalties, attorneys' fees and costs permitted by law and equity.

II. JURISDICTION AND VENUE

35. Plaintiff, Town of Wallingford, is a 39.9 square mile Connecticut town in Southern Connecticut, located in New Haven County. It is the home of a large variety of industries and major corporations spanning the spectrum of the medical, health care, service, high-tech specialty metal manufacturing and research development. As of the 2010 census, Wallingford had a population of 45,135. Plaintiff is a "municipality" within the definition of Conn. Gen. Stat. §7-148(a). Section 7-148 defines the scope of municipal powers and provides that "[a]ny municipality shall have the power to . . . sue and be sued, and institute, prosecute, maintain and defend any action or proceeding in any court of competent jurisdiction." Conn. Gen. Stat. §7-148(c)(1)(A).

36. Additionally, Conn. Gen. Stat. §7-148(c)(7)(H) gives Connecticut municipalities the power to: (1) "prohibit the carrying on within the municipality of any trade, manufacture, business or profession . . . prejudicial to public health . . . or dangerous to, or constituting an unreasonable annoyance to, those living or owning property in the vicinity"; (2) "[p]reserve the public peace and good order"; and (3) "provide for the health of the inhabitants of the municipality and do all things necessary or desirable to secure and promote the public health." *Id*. Generally, Conn. Gen. Stat. §52-73 states that: "[t]owns, societies, communities and corporations may prosecute and defend civil actions, may appoint agents to appear in their behalf and may employ attorneys in such actions."

37. The jurisdiction of this action is proper in this Court, which has original jurisdiction throughout the State in all causes of action brought under the Constitution of the State of Connecticut, article XX, §1: "Section 1 of article fifth of the constitution is amended to read as follows: The judicial power of the state shall be vested in a supreme court, an appellate court, a superior court, and such lower courts as the general assembly shall, from time to time, ordain and establish. The powers and jurisdiction of these courts shall be defined by law."

38. This Court has personal jurisdiction over Defendants because they carry on a continuous and systematic part of their general business within Connecticut, have transacted substantial business with Connecticut entities and residents, and have caused harm in Connecticut as a result of the specific business activities complained of herein.

39. Venue is proper in this Court pursuant to Conn. Gen. Stat. §51-345.

III. PARTIES

A. Plaintiff

40. Plaintiff, Town of Wallingford, provides many municipal services that are designed to foster the safety, health, and well-being of its residents, including police, fire, and first responder services, law enforcement services, judiciary services, and public health, safety and assistance services for families, teenagers, and persons in need. Due to the severity and nature of the public nuisance created and fueled by Defendants' wrongful conduct, the Town of Wallingford has been forced to expend enormous amounts of taxpayer dollars to meet the needs of its citizens and its integrity as a Town, by providing many services that are well beyond those traditionally considered to be municipal services.

41. The Town of Wallingford is also on a high deductible workers' compensation insurance plan for all its employees. Additionally, Wallingford partially self-insures for medical and health insurance for its Town employees and retirees.

42. The Town brings this action on its own behalf and as *parens patriae* in the public interest on behalf of its residents.

B. Defendants

Defendant Purdue Pharma L.P. ("Purdue")

43. Defendant Purdue Pharma L.P. ("PPL"), registered and doing business in Connecticut as Purdue Pharma (Delaware) Limited Partnership, is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut.

44. Defendant Purdue Pharma Inc. ("PPI") is a New York corporation with its principal place of business in Stamford, Connecticut.

45. Defendant The Purdue Frederick Company, Inc. ("PFC") is a New York corporation with its principal place of business in Stamford, Connecticut.

46. PPL, PPI, and PFC (collectively, "Purdue") are engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in the Town of Wallingford, including the following:

Table 1 - Purdue Opioids

Drug Name	Chemical Name
OxyContin	Oxycodone hydrochloride extended release
MS Contin	Morphine sulfate extended release
Dilaudid	Hydromorphone hydrochloride
Dilaudid-HP	Hydromorphone hydrochloride
Butrans	Byprenorphine
Hysingla ER	Hydrocodone bitrate
Targiniq ER	Oxycodone hydrochloride and naloxone

47. OxyContin is Purdue's largest-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $3.1 billion, up four-fold

from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (*i.e*., painkillers).

48. In 2007, Purdue settled criminal and civil charges brought against it by the DOJ for misbranding OxyContin and agreed to pay the United States over $600 million – at the time, one of the largest settlements with a drug company for marketing misconduct – as well as a sweeping set of injunctive relief requiring the Defendant to cease its unlawful and deceptive marketing practices. *United States of America v. Purdue Frederick Company, Inc*., Plea Agreement, No. 1:07CR00029 (W.D. Va. May 10, 2007). Simultaneously, Purdue settled an action brought by 27 States Attorneys General for $20 million and further injunctive relief.

49. Upon information and belief, Purdue has violated most, if not all, of its commitments under its consent decrees with the Government.

Defendants Teva Pharmaceuticals and Cephalon, Inc. ("Cephalon")

50. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), an Israeli corporation.

51. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc.

52. Teva USA and Cephalon, Inc. (collectively, "Cephalon") work together to manufacture, promote, distribute and sell both brand name and generic versions of opioids nationally and in the Town of Wallingford, including the following:

Table 2 – Cephalon Opioids

Drug Name	Chemical Name	Form
Actiq	Fentanyl citrate	Lollipop or lozenge
Fentora	Fentanyl citrate	Buccal tablet, like a smokeless

		tobacco plug

53. In September 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug, and Cosmetic Act for its misleading promotion of Actiq (and two other drugs) and agreed to pay $425 million in fines, damages, and penalties.

Defendants Johnson & Johnson and Janssen Pharmaceuticals ("Janssen")

54. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

55. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of J&J.

56. Defendant Ortho-McNeil-Janssen Pharmaceuticals Inc. ("OMP"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

57. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

58. Janssen Pharmaceutica, Inc. ("Janssen Pharmaceutica"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

59. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals stock. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals drugs, and Janssen Pharmaceuticals' profits inure to J&J's benefit.

60. J&J, Janssen Pharmaceuticals, OMP, and Janssen Pharmaceutica (collectively, "Janssen") are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in the Town of Wallingford, including the following:

Table 3 – Janssen Opioids

Drug Name	Chemical Name	Form
Duragesic	Fentanyl	Transdermal Patch
Nucynta (prior to 2015)	Tapentadol ER	Tablet
Nucynta ER (prior to 2015)	Tapentadol	Tablet

61. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least $1 billion in annual sales.

Defendant Endo Pharmaceuticals ("Endo")

62. Defendant Endo Health Solutions Inc. ("EHS") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

63. Defendant Endo Pharmaceuticals, Inc. ("EPI") is a wholly owned subsidiary of EHS and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

64. EHS and EPI (collectively, "Endo") manufacture, promote, distribute, and sell opioids nationally and in the Town of Wallingford, including the following:

Table 4 – Endo Opioids

Drug Name	Chemical Name	Form
Opana ER	Oxymorphone hydrochloride extended	Tablet
Opana	Oxymorphone hydrochloride and aspirin	Tablet
Percodan	Oxycodone hydrochloride and acetaminophen	Tablet release
Percocet	Oxycodone and acetaminophen	Tablet

65. Opioids comprised approximately $403 million of Endo's overall revenue of $3 billion in 2012. Opana ER yielded revenue of $1.15 billion from 2010 to 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids, both directly and through its subsidiary, Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

66. A reformulated Opana ER that had been approved in 2012 was removed from the market in June 2017, at the request of the FDA, which found that "the benefits of the drug may no longer outweigh its risks." The FDA stated, "the FDA determined that the data did not show that the reformulation could be expected to meaningfully reduce abuse and declined the company's request to include labeling describing potentially abuse-deterrent properties for Opana ER."[18]

Defendants Allergan plc f/k/a Actavis plc; Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.; Watson Laboratories, Inc.; Actavis LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. ("Actavis")

67. Allergan plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis plc acquired Allergan plc in March 2015, and the combined company changed its name to Allergan plc in June 2015. Before that, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis plc in October 2013. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc. Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these Manufacturer Defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts, and profits from the sale of

[18] News release, FDA, *FDA requests removal of Opana ER for risks related to abuse* (June 8, 2017), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm562401.htm.

Allergan/Actavis products ultimately inure to its benefit. Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to collectively as "Actavis."

68. Actavis manufactures, promotes, sells, and distributes opioids nationally and in the Town of Wallingford, including the following opioids, as well as their generic versions:

Table 5 – Actavis Opioids

Drug Name	Chemical Name	Form
Kadian	Morphine sulfate	Tablet extended release
Norco	Hydrocodone bitartrate and acetaminophen	Tablet
Duragesic	Fentanyl	Transdermal patch
Opana	Oxymorphone hydrochloride	Tablet extended release

Kadian is an extended-release tablet for "the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. and began marketing Kadian in 2009.

Defendants Mallinckrodt PLC and Mallinckrodt LLC ("Mallinckrodt")

69. Mallinckrodt PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. Mallinckrodt LLC is a limited liability company organized and existing under the laws of the State of Delaware. Since 2013, Mallinckrodt LLC has been a wholly owned subsidiary of Mallinckrodt PLC; prior to 2013, it was a wholly-owned subsidiary of Irish public limited company Covidien PLLC (formerly known as Tyco Healthcare). Mallinckrodt PLC and Mallinckrodt LLC are referred to collectively as "Mallinckrodt."

70. Mallinckrodt manufactures, promotes, sells, and distributes opioids nationally and in the Town of Wallingford, including the following opioids, as well as their generic versions:

Table 5 – Mallinckrodt Opioids

Drug Name	Chemical Name	Form
Exalgo	Hydromorphone	Tablet extended release
Xartemis	Oxycodone and acetaminophen	Tablet extended release
Roxicodone	Oxycodone	Tablet

71. Mallinckrodt also manufactures, markets and sells generic oxycodone, of which it is one of the largest manufacturers.

72. In July 2017, Mallinckrodt agreed to pay $35 million to settle allegations brought by the Department of Justice that is failed to detect and notify the DEA of suspicious orders of controlled substances.

Defendant Insys Therapeutics ("Insys")

73. Defendant Insys Therapeutics, Inc. ("Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona.

74. Since 2012, Insys has been manufacturing and selling, nationally and in the Town of Wallingford, the following opioid:

Table 6 – Insys Opioids

Drug Name	Chemical Name	Form
Subsys	Fetanyl	Sublingual spray absorbed through mucous in the mouth

75. Subsys is a highly addictive synthetic opioid mouth spray approved for treatment of cancer pain in patients who are tolerant of other opioids. Subsys is a form of fentanyl – a narcotic up to 50 times more powerful than heroin and 100 times more powerful than morphine.

76. According to Insys's 2016 Annual Report, Subsys was the most prescribed transmucosal immediate-release fentanyl, with 42% market share, which translates to nearly $300 million in annual U.S. product sales for Insys – an increase of 270% in sales over just a year. *See* Insys Annual Report filed on Form 10-K on April 3, 2017 at 1.

77. The broad sales of Subsys raised suspicions over Insys's sales practices, especially because it appeared that only 1% of Subsys sales were generated by oncologists, and the only approved use of Subsys is for a subset of cancer patients. Subsequent investigations revealed that Insys executives (including Individual Defendant named below) devised and sanctioned blatantly unlawful methods to increase sales for off-label uses, to the profound harm, including death, of many patients.

78. On December 16, 2016, six former Insys executives were indicted for their participation in an alleged "nationwide conspiracy" to give healthcare providers kickbacks in exchange for the improper prescribing of Subsys. On October 24, 2017, a superseding indictment named and incorporated Individual Defendant Kapoor for his role in Insys's alleged "nationwide conspiracy."

79. The Senate investigation into the opioid crisis generally began with an investigation into Insys, specifically. The conclusion to the initial report, *Fueling an Epidemic*, states that Insys "has repeatedly employed aggressive and likely illegal techniques to boost prescriptions for its fentanyl product Subsys. . . . [that] included actions to undermine critical safeguards in the prior authorization process[.]"[19]

[19] Minority Staff Report, U.S. HSGAC, Ranking Member's Office (Sept. 1, 2017), *Fueling an Epidemic: Insys Therapeutics and the Systemic Manipulation of Prior Authorization*, https://www.hsdl.org/?view&did=803959.

80. The Senate investigation confirmed anecdotal evidence that sales representatives were instructed to encourage their sales "targets" (the physician, physician's assistant, nurse practitioner, or staff of the medical group with whom they met) to start the patient on a higher dosage of Subsys than was approved by the FDA. The sales representatives were told to explain to the physician that the reason to start the patient at a higher dose was to improve the pain relief outcome to the patient, but the true reason was to increase Insys's revenue. There is anecdotal evidence that the "motto" among the sales force in many regions of the country, including Connecticut, was "start them high and hope they don't die." The investigation uncovered a chilling letter from an Insys sales representative to the CEO confirming that was indeed a commonly used refrain among the sales force at Insys.

81. For ease of reference, the following is a table of all Manufacturer Defendants and their opioid products:

Table 7

Purdue Opioids		
Drug Name	**Chemical Name**	
OxyContin	Oxycodone hydrochloride extended release	
MS Contin	Morphine sulfate extended release	
Dilaudid	Hydromorphone hydrochloride	
Dilaudid-HP	Hydromorphone hydrochloride	
Butrans	Buprenorphine	
Hysingla ER	Hydrocodone bitrate	
Targiniq ER	Oxycodone hydrochloride and naloxone	
Cephalon Opioids		
Drug Name	**Chemical Name**	**Form**
Actiq	Fentanyl citrate	Lollipop or lozenge
Fentora	Fentanyl citrate	Buccal tablet, like a smokeless tobacco plug
Janssen Opioids		
Drug Name	**Chemical Name**	**Form**
Duragesic	Fentanyl	Transdermal Patch
Nucynta (prior to 2015)	Tapentadol ER	Tablet
Nucynta ER (prior to 2015)	Tapentadol	Tablet
Endo Opioids		
Drug Name	**Chemical Name**	**Form**
Opana ER	Oxymorphone hydrochloride extended	Tablet
Opana	Oxymorphone hydrochloride and aspirin	Tablet
Percodan	Ocycodone hydrochloride and acetaminophen	Tablet release
Percocet	Oxymorphone hydrochloride and acetaminophen	Tablet
Actavis Opioids		
Drug Name	**Chemical Name**	**Form**
Kadian	Morphine sulfate	Tablet extended release
Norco	Hydrocodone bitartrate and acetaminophen	Tablet
Duragesic	Fentanyl	Transdermal patch
Opana	Oxymorphone hydrochloride	Tablet extended release

Table 7

Mallinckrodt Opioids		
Drug Name	**Chemical Name**	**Form**
Exalgo	Hydromorphone	Tablet extended release
Xartemis	Oxycodone and acetaminophen	Tablet extended release
Roxicodone	Oxycodone	Tablet
Insys Opioids		
Drug Name	**Chemical Name**	**Form**
Subsys	Fentanyl	Sublingual spray absorbed through mucous in the mouth

Defendant McKesson Corporation ("McKesson")

82. Defendant McKesson Corporation is registered with the Connecticut Secretary of State as a company incorporated under the laws of Delaware with its principal place of business located in San Francisco, California. McKesson is the largest pharmaceutical distributor in North America; it delivers approximately one-third of all pharmaceuticals used in North America. McKesson conducts business in the State of Connecticut by distributing prescription opioids to hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions ("Retail End Users"). McKesson is subject to federal and state reporting obligations with respect to the distribution of controlled substances to the State of Connecticut. *See* 21 U.S.C. §§801, *et seq.*; Conn. Gen. Stat. §21a-70.

Defendant AmerisourceBergen Drug Corporation ("ABC")

83. Defendant AmerisourceBergen Drug Corporation is registered with the Connecticut Secretary of State as a company incorporated under the laws of Delaware with its principal place of business located in Chesterbrook, Pennsylvania. ABC is the second largest pharmaceutical distributor in North America. ABC conducts business in the State of Connecticut by distributing prescription opioids to Retail End Users. ABC is subject to federal reporting

obligations with respect to the distribution of controlled substances to the State of Connecticut. *See id.*

Defendant Cardinal Health, Inc. ("Cardinal")

84. Defendant Cardinal Health, Inc. is registered with the Connecticut Secretary of State as a company incorporated under the laws of Ohio with its principal place of business located in Dublin, Ohio. Cardinal is the third largest distributor of pharmaceuticals in North America. Cardinal conducts business in the State of Connecticut by distributing prescription opioids to Retail End Users. Cardinal is subject to federal reporting obligations with respect to the distribution of controlled substances to the State of Connecticut. *See id.*

C. Individual Defendant

85. Defendant John Kapoor ("Kapoor") is the founder, former Chairman of the Board and Chief Executive Officer ("CEO") of Insys Therapeutics, Inc. He remains the majority stockholder of the company. Kapoor was indicted in Boston federal court on October 24, 2017 on charges of conspiracies to commit racketeering pursuant to 18 U.S.C. §1962(d), mail fraud pursuant to 18 U.S.C. §1349, wire fraud pursuant 18 U.S.C. §1349 and violate the Anti-Kickback Law pursuant to 18 U.S.C. §371. The indictment arose from the practice of Insys which, upon information and belief, was devised by Individual Defendant Kapoor, along with some other Insys executives, of paying kickbacks to doctors to write large numbers of prescriptions. Kapoor is a citizen of the State of Arizona.

IV. FACTUAL ALLEGATIONS

A. The Scientific Basis for Pain-Relieving and Addictive Properties of Opioids

1. Similarity Between Prescription Opioids and Heroin

86. The medicinal effects of opium, an extract from the flowering poppy plant, to relieve pain and often cause euphoria, have been known for thousands of years.

87. In the early 1800s, a German pharmacist, Freidrich Sertürner, isolated a molecule from opium and named it "morphine" for its hypnotic as well as analgesic properties.

88. The late 1800s and early 1900s saw a plethora of semi-synthetic opioids that were easily derived by manipulating the basic morphine structure. Semi-synthetic opioids produce a more rapid effect than morphine because they cross the blood-brain barrier more easily.

89. One of the first semi-synthetic opioids, heroin, began being manufactured in the late 19th century. In 1914, the Harrison Narcotics Tax Act imposed a tax on those making, importing, or selling any derivative of opium. By the 1920s, physicians were aware of the highly addictive nature of opioids and tried to avoid treating patients with them. Heroin became illegal in 1924.

90. Other semi-synthetic opioids such as oxycodone, hydrocodone, oxymorphone and hydromorphone continued to be designed in labs and approved for restricted medical uses. All the opioids sold by Manufacturer Defendants Purdue, Endo, Actavis, and Mallinckrodt fall within these categories. (*See* Table 7, ¶81, *supra*).

91. In 1960 a fully synthetic opioid, named fentanyl, was synthesized by Dr. Paul Janssen in Belgium.

92. Fetanyl has been produced in various forms, including lollipops (Actiq) and a spray absorbed through the mouth (Subsys). The products of Cephalon, Janssen and Insys (listed on Table 7, ¶81, *supra*) are fentanyl or fentanyl-based synthetic opioids.

93. All these opioids, semi-synthetic opioids and the fully synthetic opioids work on a patient in very similar ways. They react with opioid receptors in the brain of the patient and are

considered "full agonists." "Agonists interact with a receptor to produce a maximal response from that receptor."[20]

94. When a full agonist opioid interacts with the opioid receptor, there is a cascade of reactions, ultimately leading to an increase in the release of dopamine in the brain.[21]

95. Opiate receptor stimulation by opioids can relieve pain and produce euphoria. These effects have been understood for millennia as properties of opium.

96. However, a known result of the physiological process for all the opioids (just as it has been for millennia with the opium from the poppy plant) is that, tolerance and dependence develop rapidly if taken on a daily basis.

97. Tolerance results in the need to take higher doses to achieve the same effect.

98. Dependence results in dysphoria, increased pain sensitivity, anxiety and flu-like symptoms when opioids are discontinued. These symptoms lead to cravings to continue use.

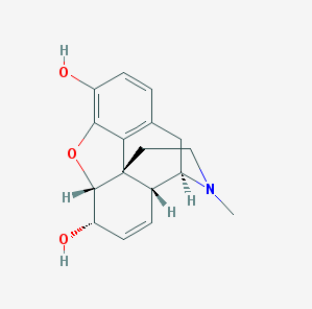
99. Commonly prescribed opioids produce effects that are indistinguishable from the effects produced by other semi-synthetic opioids.

---

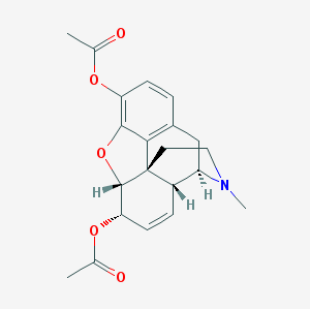
[20] Hasan Pathan & John Williams, *Basic opioid pharmacology: an update*, 6(1) BR. J. PAIN 11-16 (2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4590096/.

[21] Nora D. Volkow, M.D., *et al*., *Neurobiologic Advances from the Brain Disease Model of Addiction*, 374 NEW ENG. J. MED. 363 (2016), http://www.nejm.org/doi/full/10.1056/NEJMra1511480#t=article.

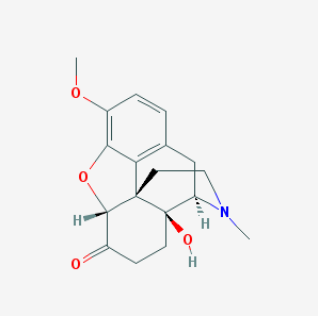
Morphine[22]



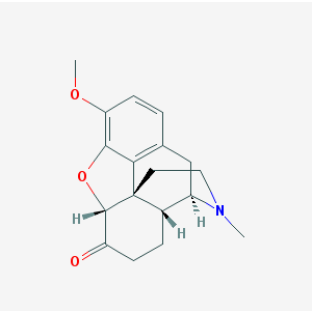
Heroin[23]



Oxycodone[24]
(sold as Percocet, OxyContin)



Hydrocodone[25]
(sold as Vicodin)



Oxymorphone[26]
(sold as Opana)

Hydromorphone[27]
(sold as Dilaudid)

---

[22] NIH, NAT'L CTR. FOR BIOTECHNOLOGY INFO., PubChem Compound Database; CID=5288826, https://pubchem.ncbi.nlm.nih.gov/compound/5288826 (last visited on Feb. 13, 2018).

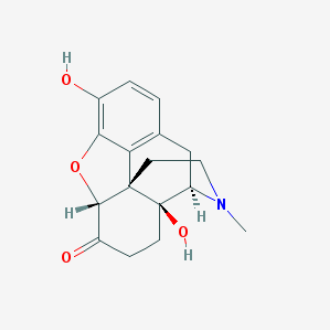
[23] *Id.*; CID=5462328, https://pubchem.ncbi.nlm.nih.gov/compound/5462328 (last visited on Feb. 13, 2018).

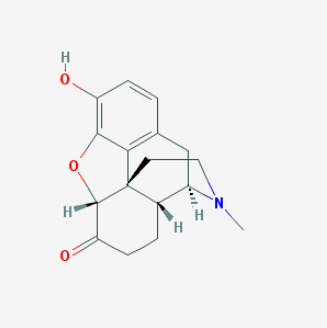
[24] *Id.*; CID=5284603, https://pubchem.ncbi.nlm.nih.gov/compound/5284603 (last visited on Feb. 13, 2018).

[25] *Id.*; CID=5284569, https://pubchem.ncbi.nlm.nih.gov/compound/5284569 (last visited on Feb. 13, 2018).

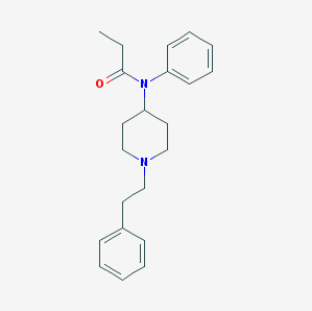
[26] *Id.*; CID=5284604, https://pubchem.ncbi.nlm.nih.gov/compound/5284604 (last visited on Feb. 13, 2018).

[27] *Id.*; CID=5284570, https://pubchem.ncbi.nlm.nih.gov/compound/5284570 (last visited on Feb. 13, 2018).





Fentanyl[28]
(sold as Subsys)



100. It is simple to see from these charts how chemically similar the natural morphine, heroin, and the semi-synthetic opioids are to one another. The opioid pain relievers ("OPRs") all share the same five-ring structure that allows them to react with opioid receptors in the brain. While Fetanyl and other synthetic opioids do not share the same five-ring structure, they nevertheless interact with opioid receptors in the brain the same way. Dr. Andrew Kolodny, Senior Scientist and Co-Director of Opioid Policy Research at the Heller School for Social Policy and Management, and co-founder of Physicians for Responsible Opioid Prescribing, called prescription opioids "heroin pills."[29]

---

[28] *Id.*; CID=3345, https://pubchem.ncbi.nlm.nih.gov/compound/3345 (last visited on Feb. 13, 2018).

[29] Dr. Andrew Kolodny, Statement before the U.S. Senate, Caucus on International Narcotics Control, One Hundred Thirteenth Congress, Second Session, *America's Addiction to*

> Like heroin, most OPRs are made from opium. Their molecular structure is nearly identical to that of heroin and the effects they produce in the brain are indistinguishable from heroin. What this means is that when we talk about OPRs, we are essentially talking about "heroin pills."

101. Commonly prescribed opioid analgesics have the same pain-relieving, euphoria-inducing, intensely addictive qualities of morphine and heroin.

102. A Columbia University study found that experienced heroin users preferred the effects of oxycodone over the effects of heroin.[30]

2. Biology of Why a Person with a Prescription Opioid Addiction Frequently Turns to Street Drugs

103. With daily use of opioids, in as little as one week, patients can experience withdrawal symptoms if opioids are discontinued (commonly referred to as "dependence"). Once dependent, cessation of use produces deeply unpleasant symptoms such as nausea, vomiting, headaches, tremors, insomnia, and pain.

104. Dr. Kolodny has explained the effect of opioids as akin to "hijack[ing] the brain's reward system," which in turn convinces a user that "the drug is needed to stay alive."[31]

105. When under the continuous influence of opioids over a period of time, patients grow tolerant to the analgesic or pain-relieving effects. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same levels of pain reduction

---

Opioids: Heroin and Prescription Drug Abuse (May 14, 2014), at 2, https://www.drugcaucus.senate.gov/content/senate-caucus-international-narcotics-control-hearing-america%E2%80%99s-addiction-opioids-heroin-and.

[30] Sandra D. Comer, Ph.D., *et al*., NCBI, *Relative abuse liability of prescription opioids compared to heroin in morphine-maintained heroin abusers* (June 20, 2007), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3787689/.

[31] David Montero, *Actor's death sows doubt among O.C.'s recovering opioid addicts*, THE ORANGE CNTY. REGISTER (Feb. 4, 2014), http://www.ocregister.com/articles/heroin-600148-shaffer-hoffman.html.

he or she has become accustomed to – up to and including doses that are considered to be "frighteningly high."[32] At higher doses, the effects of withdrawal are more substantial, and the risk of addiction increases. The FDA has acknowledged that available data suggests a relationship between increased doses and the risk of adverse effects.[33]

106. As addiction science shows, once an individual is addicted to any of these products, a series of biochemical reactions and physiological changes in the brain make it very difficult to break the addiction, even if the patient desperately wants to do so. These known brain changes in addicted persons also explain why addiction is a relapsing disease.

107. As the NEW ENGLAND JOURNAL OF MEDICINE explains:

> This attenuated release of dopamine renders the brain's reward system much less sensitive to stimulation by both drug-related and non-drug-related rewards. As a result, persons with addiction no longer experience the same degree of euphoria from a drug as they did when they first started using it. It is for this same reason that persons with addiction often become less motivated by everyday stimuli (e.g., relationships and activities) that they had previously found to be motivating and rewarding. Again, it is important to note that these changes become deeply ingrained and cannot be immediately reversed through the simple termination of drug use (e.g., detoxification).[34]

108. As addiction deepens, the changes in the brain of the addict become more profound. The deadened mood affect and pre-occupation with continued use to the exclusion of previously pleasurable activities are aggravated by a lessened ability to control impulses. Further,

> [t]he changes that occur in the reward and emotional circuits of the brain are accompanied by changes in the function of the prefrontal cortical regions, which

---

[32] Mitchell H. Katz, M.D., *Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith*, 170(16) ARCHIVES OF INTERNAL MED. 1422 (2010). https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/225880?redirect=true.

[33] N. Volkow, *supra* at n.21.

[34] *Id*.

> are involved in executive processes. Specifically the down-regulation of dopamine signaling that dulls the reward circuits' sensitivity to pleasure also occurs in prefrontal brain regions and their associated circuits, seriously impairing executive processes, among which are the capacities for self-regulation, decision making, flexibility in the selection and initiation of action, attribution of salience (the assignment of relative value), and the monitoring of error.[35]

109. Recent research on the brains of addicted individuals makes clear why that person would substitute heroin for prescription opioids, and further, why the changes in the individual's brain caused by the addiction to prescription opioids makes it almost impossible to resist the need for continued use, even to the point of death.

110. In short, the progression of addiction is, first, the initial pain relief and feeling of well-being or euphoria experienced by the patient. Next is the craving for more and more of the substance, since the dopamine rewards system has been hijacked and the patient is incapable of experiencing everyday joys. Even greater and more frequent amounts of the opioid do not work, since the patient's dopamine reward system is broken. As addiction proceeds, the patient becomes increasingly incapable of thinking through the situation, since his prefrontal cortical regions have become affected. Therefore, a person who has become addicted to opioids feels compelled to continue using and will switch to heroin if it is easier and less expensive to obtain.

3. Biology of Why a Person with an Opioid Addiction Frequently Turns to Crime[36]

111. Opioid addiction is different from other chronic diseases. The opioid-addicted individual will behave in ways that appear anti-social. Even a threat of severe punishment is insufficient to keep them from continuing their opioid use. They will give up everything and

---

35 *Id*.

36 Nora D. Volkow, *et al*., *Addiction: Decreased reward sensitivity and increased expectation sensitivity conspire to overwhelm the brain's control circuit*, NIH Public Access (Sept. 2010).

everyone they have ever cared about to maintain their opioid supply. The anti-social behavior that opioid-addicted individuals engage in is not driven by character flaws or moral failing. Instead, the behavior is secondary to the development of addiction. Once addicted, good people will behave in ways they never could have imagined.

112. When an opioid is taken regularly, regions of the brain that modulate behavior and control our higher functions like judgment, decision making, and self-control over our actions begin to change in ways that may be irreversible. In effect, opioids hijack critical regions of the brain causing a loss of free will. The result is the person needs to continue using an opioid to avoid feeling dysphoria.

113. Opioid addiction is a disease of exposure. Repeated use of opioids, even when taken exactly as prescribed, can result in addiction. The sharp increase in opioid prescribing over the past 20 years has led to parallel increases in opioid addiction and overdose deaths. Overprescribing causes addiction directly in patients prescribed opioids. And overprescribing causes addiction indirectly, as patients' prescriptions are borrowed by or shared with family members and friends..

B. Lack of Evidence that Long-Term Opioid Use Was a Valid Pain Treatment

114. Manufacturer Defendants have always been aware that there was no real evidence of the safety and efficacy of opioids for long-term use. To the contrary, there was evidence that, with long-term use, opioid drugs would become less effective because of tolerance to the pain relieving effects.

115. A 2006 study-of-studies found that opioids as a class did not demonstrate improvement in "function" over other non-addicting treatments. It stated: "For functional outcomes, the other analgesics were significantly more effective than were opioids.[37]

116. Endo's own research shows that patients taking opioids, as opposed to other prescription pain medicines, report higher rates of obesity (30% to 39%); insomnia (9% to 22%); and self-described fair or poor health (24% to 34%).

117. In the fall of 2009, as a pain specialist noted in an article titled *Are we making pain patients worse?*, "[O]pioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[38]

118. Workers' compensation data has also long revealed the lack of evidence for the efficacy of opioids for long-term chronic pain. Claims involving workers who take opioids are almost four times as likely to reach costs of over $100,000 than claims without opioids, as these patients suffer greater side effects and are slower to return to work. Even adjusting for injury severity and self-reported pain score, receiving an opioid for more than seven days and receiving

---

[37] Andrea D. Furlan, *et al*., *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) CAN. MED. ASS'N J. 1589 (2006) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1459894/. This same study revealed that efficacy studies do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are pre-screened out of the study pool. This does not reflect how doctors actually prescribe the drugs, because even patients who have past or active substance use disorders tend to receive higher doses of opioids. Karen H. Seal, *et al*., *Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. AM. MED. ASS'N 940 (2012).

[38] Andrea Rubenstein, M.D., *Are we making pain patients worse?*, SONOMA MEDICINE (Fall 2009), http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse.aspx?pageid=144&tabid=747.

more than one opioid prescription increased the risk that the patient would be on work disability one year later. A prescription for opioids as the first treatment for a workplace injury doubled the average length of the claim.

119. In the face of this body of evidence and medical orthodoxy questioning the efficacy and safety of opioids, the Manufacturer Defendants mounted their disinformation campaign to open the market for their drugs, despite the known risk of addiction.

C. Campaign of Misinformation and Unlawful Conduct by Manufacturer Defendants

1. Summary of Manufacturer Defendants' Disinformation Campaign

120. Manufacturer Defendants, through a sophisticated and highly deceptive and unfair marketing campaign that began in the late 1990s and continues to the present, set out to and succeeded in reversing the popular and medical understanding of opioids. Chronic opioid therapy – the prescribing of opioids to treat chronic pain long-term – is now a commonplace and highly dangerous practice in the United States.

121. Since Insys did not begin selling its fentanyl-based product, Subsys, until 2012, it did not participate in the activity preceding that date. Although Insys may not have participated in the collusive campaign of the other Manufacturer Defendants to change medical orthodoxy solely for reasons of greed rather than any scientific basis, it profited enormously from the deception that opioids could be safe for long-term use. Moreover, Insys engaged in outrageously fraudulent practices to sell its drug, Subsys, resulting in indictments of six of its executives, including Individual Defendant Kapoor, and untold deaths and devastation to Americans, including residents of Wallingford.

122. To accomplish this reversal, Manufacturer Defendants spent hundreds of millions of dollars: (a) developing and disseminating ***seemingly truthful*** scientific and educational

materials and advertising that misrepresented the risks, benefits, and superiority of opioids for treating chronic pain; (b) funding, assisting, encouraging, and directing KOLs to deliver scripted talks, publish misleading studies, and present CMEs that disseminated false and incomplete information to medical practitioners; (c) infiltrating the boards and committees of professional societies and patient advocacy groups that delivered messages and developed guidelines supporting chronic opioid therapy; (d) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to as "Front Groups") that developed misleading educational materials and treatment guidelines that were then distributed by Distributor Defendants, urging doctors to prescribe, and patients to use, opioids long-term to treat chronic pain; (e) deploying sales representatives who visited doctors and other prescribers who marketed their opioids for "non-indicated" or off-label purposes, not approved by the FDA, thereby violating 21 U.S.C. §§331(a)-(b), 352(a); and (f) targeting public ads to vulnerable populations such as the elderly and veterans.

123. Manufacturer Defendants: (a) overstated the benefits of chronic opioid therapy, promised improvement in patients' function and quality of life, and failed to disclose the lack of evidence supporting long-term use; (b) trivialized or obscured opioids' serious risks and adverse outcomes, including the risks of addiction, overdose, and death; (c) overstated their superiority compared with other treatments, such as other, non-opioid analgesics, physical therapy, and other alternatives; and (d) mischaracterized the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms. There is not, and there never has been, reliable scientific evidence to support Manufacturer Defendants' marketing claims. There has long been, and there continues to be, substantial scientific evidence that these claims are false.

2. False Messaging

a. Drug Companies Must Deal Honestly with Patients, Consumers, and Governmental Payors

124. Like every other business in Connecticut, pharmaceutical manufacturers have a duty to deal honestly and truthfully with consumers and to refrain from using unfair and deceptive acts to boost profits at the consumer's expense.

125. A drug company's representations about its drug must: (a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance the drug's benefits and risks.

126. Furthermore, drug companies are not permitted to sell any drugs that are "misbranded," which means, among other things, that the "label" cannot be false or misleading. "Labeling" includes more than the drug's physical label; it also includes "all . . . other written, printed, or graphic matter . . . accompanying" the drug, including promotional material.[39] The term "accompanying" includes promotional materials – posters, websites, brochures, books, etc. that are disseminated by or on behalf of the manufacturer of the drug.[40] Thus, Manufacturer Defendants' promotional materials are part of their drugs' labels and required to be accurate, balanced, and not misleading.

127. Labeling is misleading if it is not based on substantial evidence, if it materially misrepresents the benefits of a drug, or if it omits material information about or minimizes the frequency or severity of a product's risks. Promotion that fails to present the most important risks of a drug as prominently as its benefits lacks fair balance and is therefore deceptive.

---

39 21 U.S.C. §321(m).

40 *See id.*; Notes of Decisions, Accompanying the article, labeling.

128. Drug companies are also prohibited from distributing evidence or information about a drug's safety or efficacy, or presenting conclusions that "clearly cannot be supported by the results of the study."[41] Drug companies further must not make comparisons between their drugs and other drugs that represent or suggest that "a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience."[42]

129. The Manufacturer Defendants' responsibilities to not engage in false, untrue, misleading and deceptive statements of material fact to physicians, consumers, payors, and Plaintiff, the Town of Wallingford, are consistent with their duties under CUTPA, Conn. Gen. Stat. §42-110, *et seq.*, and the FDCA. Plaintiff expressly denies that the reference to the FDCA in this Complaint means that any claims "arise under" the federal law within the meaning of 28 U.S.C. §1331.

130. Manufacturer Defendants long maintained that prescription opioids carry little to no risk of addiction, when they knew that not to be true. For example, Purdue claimed that the risk of addiction was negligible, even though its own studies had shown that between 8% and 13% of OxyContin patients became addicted.

131. Manufacturer Defendants have said that specific characteristics of their drugs made them less addictive, when there was no evidence to support their assertions. For example, Endo marketed Opana ER as being crush-resistant, and as a result, hard to abuse, and harder to become addicted to. In fact, Endo knew that there was no evidence to support this assertion. Sales representatives for Purdue, Janssen, Endo and Actavis promoted their drugs as having

---

41 21 C.F.R. §99.101(a)(4).

42 21 C.F.R. §202.1(e)(6)(ii).

"steady-state" properties with the intent and expectation that prescribers would understand this to mean that their drugs caused less of a rush or a feeling of euphoria, which can trigger misuse and addictions.

132. Cephalon-sponsored *Treatment Options: A Guide for People Living with Pain* (American Pain Foundation, 2007) stated that addiction is limited to extreme cases of unauthorized dose escalations, getting opioids from multiple sources, or theft. In truth, Cephalon knew there was no basis for this depiction that addiction occurred only in rare cases.

133. Manufacturer Defendants have maintained that addiction risk can be managed by the prescribing physician by asking patients to fill out a questionnaire to assess their risk of addiction (known as "screening"). Actavis trained its sales force that prescribers can use risk screening tools to limit the development of addiction. However, there is not, and there never has been, evidence to suggest that such screening is reliable.

134. Manufacturer Defendants falsely suggested or even blatantly proclaimed that withdrawal from opioids was not a problem. Actavis trained its sales force to assert that discontinuing opioid therapy can be handled "simply" and done at home, with the withdrawal period approximately taking a week, even in addicted patients. Janssen training materials between 2009 and 2011 repeatedly proclaimed "low incidence of withdrawal symptoms" as a "core message" for their sales force. In addition to claiming a low rate of withdrawal symptoms, Janssen relied upon a study that only began tracking withdrawal symptoms in patients two to four days after discontinuing opioid use. Janssen knew or should have known that these symptoms peak earlier than that for most patients.

135. Contrary to Manufacturer Defendants' assertions, opioids have been found time and again to be addictive. A patient's fear of the unpleasant effects of discontinuing opioids,

combined with the negative reinforcement during a period of actual withdrawal, can push a patient to seek further opioid treatment – even where ineffective or detrimental to quality of life – simply to avoid the deeply unpleasant effects of withdrawal.

b. Falsehood: No Upper Limit on Amount of Opioids to Consumer

136. Manufacturer Defendants have misrepresented and even denied entirely the dangers posed by large doses of opioids. Manufacturer Defendants claimed that dosages could be escalated continuously to match high pain tolerance, even though studies showed that such escalation could be deadly. This false advice has been disseminated even though the Manufacturer Defendants, their executives, researchers, and sales staff have knowledge that increasing a dosage or starting a patient with a high dosage may be fatal. *See supra* at ¶¶80.

137. This falsehood is of particular concern because none of the Manufacturer Defendants' opioids has a cap on dosage. Thus, the guidance of manufacturers (and the medical community, informed by manufacturers) has a critical role to play in preventing overdose.

138. There is not now, and there never has been, any scientifically based support for the Manufacturer Defendants' statements that there are no upper limits for opioids.

139. High doses pose real risk. The 2016 CDC Guidelines states in pertinent part: "[b]enefits of high-dose opioids for chronic pain are not established," while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." It further states there are "increased risks for opioid use disorder, respiratory depression, and death at higher dosages[.]" As a result the CDC advised doctors to "avoid increasing dosage" above 90 morphine milligram equivalents per day.

140. When under the continuous influence of opioids over time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher

doses to obtain the same levels of pain reduction to which he or she has become accustomed – up to and including doses that are "frighteningly high."[43] *Supra* at ¶105. At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of addiction. A patient can take the opioids at the continuously escalating dosages to match pain tolerance and still overdose at recommended levels.

c. Falsehood: Opioids Are the Best Solution

141. Manufacturer Defendants have consistently exaggerated the benefits and downplayed the side effects of opioids as compared to other analgesics. Specifically, Manufacturer Defendants have ignored the effects of long-term opioid therapy, which include addiction, hyperalgesia, hormonal dysfunction, decline in immune function, increased bone fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interaction with other medication taken to treat disorders frequently co-existing with chronic pain. At the same time, Manufacturer Defendants have greatly exaggerated the incidence of side-effects and the risk of death from medicines such as aspirin or ibuprofen, technically known as non-steroidal anti-inflammatory drugs ("NSAIDs"). Manufacturer Defendants have suggested 10,000-20,000 annual deaths are attributable to NSAIDs, when the real number is approximately 3,200 and shrinking.[44]

142. On the contrary, there is evidence that opioid drugs are less effective at treating chronic pain, and may worsen patients' health. As noted, a comprehensive study in 2006 found that opioids as a class did not demonstrate improvement in functional outcomes over other non-

---

[43] M. Katz, *supra* at n.32.

[44] *See* Courtney Krueger, PharmD, BCPS, *Ask the Expert: Do NSAIDs Cause More Deaths Than Opioids?*, PRACTICAL PAIN MGMT. (Nov./Dec. 2013), https://www.practicalpainmanagement.com/treatments/pharmacological/opioids/ask-expert-do-nsaids-cause-more-deaths-opioids.

addicting treatments. Rather, the study concluded: "[f]or functional outcomes, the other analgesics were significantly more effective than were opioids."[45] The above study and similar ones that were antithetical to the position of the Manufacturer Defendants were simply not presented by the KOLs in their speeches to practitioners, in the lectures presented at CMEs controlled by the Manufacturer Defendants, or in the Front Groups used to disseminate the Manufacturer Defendants' false message that opioids are a superior pain treatment.

143. The Manufacturer Defendants knew their disparagement of NSAIDs and other analgesics was unfounded. Indeed, Endo's own internal research shows that patients taking opioid-based pain medicines specifically reported higher rates of obesity, insomnia, and self-described fair or poor health.

d. Falsehood: The Promise of a Pain-Free Life and Vigorous Existence

144. Manufacturer Defendants misrepresented that opioids improve functioning over time. For example, Janssen sponsored a patient education guide in 2009, *Finding Relief: Pain Management for Older Adults*, which states as a fact that "opioids may make it easier for people to live normally."

145. There is not, and there never has been, any data to support the claim that they do so; in fact, there is data to suggest that long-term opioid usage reduces functioning. Data from workers' compensation claims indicates that there is a negative correlation between opioid prescriptions and a person returning to work.[46]

---

45 Furlan, *supra* at n.37.

46 *See, e.g.*, Cindy L. Kidner, *et al.*, *Higher Opioid Doses Predict Poorer Functional Outcome in Patients with Chronic Disabling Occupational Musculoskeletal Disorders*, 91(4) J. BONE JOINT SURG. AM. 919-27 (Apr. 1, 2009).

146. The 2016 CDC Guidelines (¶23, *supra*) state that "[a]lthough opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy." The CDC further found that "evidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

e. Falsehood: Tapering Is an Effective Way to Manage Any Withdrawal

147. Manufacturer Defendants also falsely represent that withdrawal is easily managed, for example, by tapering off a patient's dosage. For instance, Endo's CME *Persistent Pain in the Older Adult* taught that withdrawal can be avoided by tapering off dosage by 10-20% daily for ten days.

148. The 2010 Mallinckrodt/C.A.R.E.S. publication "Defeat Chronic Pain Now!" advised potential opioid users that tolerance to opioids is "easily remedied," and that "[a]ll patients can be safely taken off opioid medication if the dose is slowly tapered down by their doctor."[47]

149. Janssen's training materials asserted that Nucynta ER has a low incidence of withdrawal symptoms, based on a study of withdrawal symptoms two to four days after discontinuing use (when, in fact, the symptoms peak earlier than that).

150. On its current website, PrescribeResponsibly.com, in an article titled *What a Prescriber Should Know Before Writing the First Prescription*, Janssen states that opioid

[47] Charles E. Argoff & Bradley S. Galer, *Defeat Chronic Pain Now!* (2010).

addiction "can usually be managed" with such tools as Opioid Agreements between the prescribing physician and patient.

151. There is no reliable data, nor has there ever been, supporting the statements made by each Manufacturer Defendant that gradual tapering would alleviate the risk of withdrawal.

f. Falsehood: Pseudoaddiction

152. Pharmaceutical manufacturers tried to dismiss signs of addiction in patients by using the term "pseudoaddiction," invented by Dr. David Haddox, later Vice President of Health Policy at Purdue. Pseudoaddiction was a term used for patients showing signs of addiction; Defendants explained that what these patients were actually exhibiting was "under-treated pain."

153. With no reliable data, the Manufacturer Defendants grabbed hold of the concept of pseudoaddiction, with the intent and result that treating physicians would ignore signs of actual addiction in their patients (such as seeking early refills, agitation, etc.). Instead of advising the treating physician that the patient is likely in the throes of addiction, the Manufacturer Defendants advocated that the patient is still undertreated and should be prescribed a higher potency of the opioid.

154. Janssen sponsored, funded and edited a website publication entitled *Let's Talk Pain*, which stated "pseudoaddiction refers to patient behaviors that may occur when pain is under-treated . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

155. While the term "pseudoaddiction" is no longer prevalent and is not currently posted on any of the Manufacturer Defendants' websites, it was in common use and widely disseminated to physicians through at least 2012. Upon information and belief, as a result of the Manufacturer Defendants' false information campaign, the signs of addiction in opioid-treated patients are still being misconstrued as pseudoaddiction in the community of practicing

physicians, including those physicians in Connecticut who serve the population of the Town of Wallingford.

156. There never was any scientifically valid evidence for the concept of pseudoaddiction. The Manufacturer Defendants knew there was no scientific basis for the concept. The statements about it by the Manufacturer Defendants were false when made.

3. Means of Disinformation

157. Manufacturer Defendants strengthened the effects of their misinformation by disseminating it through varied sources in a number of settings, targeting both doctors and patients.

158. Manufacturer Defendants have poured significant resources into branded advertisements for their own particular opioids. In 2011, Manufacturer Defendants spent over $14 million advertising in medical journals, including $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.[48]

159. These advertisements have been run in publications aimed at pain specialists (*e.g.*, JOURNAL OF PAIN, CLINICAL JOURNAL OF PAIN) as well as those aimed at the entire medical community (*e.g.*, JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION).

160. These advertisements have contained misleading claims about Manufacturer Defendants' opioid products. For example, a 2005 Purdue advertisement in the JOURNAL OF PAIN described OxyContin as an "around-the-clock analgesic . . . for an extended period of time." The advertisement featured a man and boy fishing and proclaimed that *There Can Be Life With Relief*, falsely suggesting (on both counts) that OxyContin provides effective long-term

[48] While Actavis spent less than $100,000 and Cephalon spent nothing on medical advertisement in 2011, these companies' expenditures peaked earlier, with Actavis spending $11.7 million in 2005 and Cephalon spending about $4 million over 2007 and 2008.

pain relief and functional improvement. Endo's Opana ER was advertised with photos of people engaged in demanding jobs, suggesting that the drug could provide long-term relief and functional improvement.

161. Since Insys entered the opioid pain market in 2012, after many of these means to disseminate false information were already under way, it is not known at this time to what extent Insys participated in them. Upon information and belief, Insys was able to effectively sell Subsys off-label due to the wide dissemination of misinformation propagated by the other Manufacturer Defendants.

a. Unsupported Research

162. Manufacturer Defendants have misrepresented scientific research and evidence surrounding the addictiveness of their pharmaceutical products.

163. Manufacturer Defendants led people to reasonably believe that they had tested the safety and efficacy of opioids for long-term use, by creating a body of false, misleading, and unsupported literature about opioids that appeared to be the result of independent, objective research, and was thus more likely to shape the perceptions of prescribers, patients and payors.

164. Manufacturer Defendants coordinated the timing and publication of manuscripts, abstracts, posters and oral presentations, and educational materials in peer-reviewed journals and other publications to support the launch and sales of their drugs. Manufacturer Defendants' internal documents show plans to submit research papers and "studies" to long lists of journals, including back-up options and last resort, "fast-track" application journals, that they could use if the pending paper was rejected everywhere else.

165. Manufacturer Defendants worked to ensure that favorable articles were disseminated and cited widely in medical literature, even where references distorted the significance or meaning of the underlying study. One of the most frequently used distortions is

the instance of a five-sentence letter written to the NEW ENGLAND JOURNAL OF MEDICINE ("NEJM") in 1980 by Dr. Hershel Jick and his assistant, Ms. Jane Porter.

166. In 1980, Dr. Jick and his assistant, Ms. Porter, who both worked at the Boston University Medical Center, sent the Porter/Jick Letter to the prestigious NEJM:

> ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS
>
> To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients, Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.
>
> Jane Porter
> Hershel Jick, M.D.
> Boston Collaborative Drug
> Surveillance Program
> Boston University Medical Center
> Waltham, MA 02154.[49]

167. Manufacturer Defendants and their Front Groups have twisted this letter and misused it as scientific confirmation for their assertion that widespread and long-term opioid use does not pose a substantial threat of addiction. The Manufacturer Defendants knew, but failed to disclose, the material information that undermined the validity of the five-sentence letter for the sweeping proposition for which it was cited.

168. Manufacturer Defendants knowingly misrepresented the findings and scientific value of the letter in several ways:

---

[49] J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302(2) NEW ENG. J. MED. 123 (1980), www.nejm.org/doi/pdf/10.1056/NEJM198001103020221.

(a) By omitting the fact that Ms. Porter and Dr. Jick's observations were made in a letter to the editor, and implying – or outright stating – that the results were the published results of a peer-reviewed scientific clinical trial study, they misrepresented the scientific validity of its findings;

(b) Based on when the letter was written, in 1980, the use of opioids being described in the letter could only have been for acute pain or for end-of-life care because medical practice at the time prohibited opioids from being used to treat chronic pain. Nevertheless, Manufacturer Defendants cited the Porter/Jick Letter as evidence for the proposition that opioids pose a low risk of addiction in all contexts, including long-term use for chronic pain;

(c) Since the Porter/Jick Letter is not based on a clinical trial, there is no level of confidence that patients were regularly being monitored for signs of addiction. Thus, there may have been false negatives;

(d) The letter is written about patients who were given a few opioid doses ***in a hospital***, rather than those who were given prescriptions to take home. Nonetheless, it was trumpeted by Manufacturer Defendants as scientific evidence that opioids pose a low risk of addiction when used long-term; and

(e) There is no evidence that these patients were followed up with after leaving the hospital regarding the presence of any addiction. But it was cited by Manufacturer Defendants as showing that opioids pose no long-term risk of addiction.

169. Manufacturer Defendants mis-cited the Porter/Jick Letter again and again as evidence of the minimal risk of addiction from using opioids as a treatment for chronic pain,

despite its limited credibility, and despite the existence of much more significant evidence to the contrary.

170. Two papers funded by Purdue in 1998 showed that between 8% and 13% of patients studied subsequently became addicted to opioids. Ignoring this study, the Porter/Jick Letter was cited and relied upon in two CME courses put on by Purdue and Endo in 2012 to support the assertion that opioids are not addictive.

171. The Porter/Jick Letter was not extensively cited as evidence of opioids' low risk of addiction until it first appeared in a 1986 paper by the American Pain Society, one of Defendants' Front Groups. From there its use as a tool of misinformation mushroomed. It has been cited over 600 times, in contrast to the other 11 letters to the editor published in the NEJM contemporaneously, which were cited a median of 11 times.

172. Dr. Hershel Jick, the primary author, later stated that his own letter had been misused and distorted. He has said that he is "mortified that that letter to the editor was used as an excuse to do what these drug companies did," referring to the fact that "they used this letter to spread the word that these drugs were not very addictive."[50]

173. A 2017 statement in the NEJM (probably the first of its kind) was published as a meta-study on the misuse of the letter. It says that the letter "was heavily and uncritically cited as

[50] Derek Hawkins, *How a short letter in a prestigious journal contributed to the opioid crisis*, WASHINGTON POST (June 2, 2017), https://www.washingtonpost.com/news/morning-mix/wp/2017/06/02/how-the-opioid-crisis-traces-back-to-a-five-sentence-scholarly-letter-from-1980/?utm_term=.836d02c52301.

evidence that addiction was rare with long-term opioid therapy," which statement "contributed to the North American opioid crisis[.]"[51]

174. The 2017 study reports that 80.8% of articles citing the 1980 letter did not mention that it was limited to the hospital setting, and 72.2% of articles citing it used it to support the conclusion that addiction is rare in patients treated with opioids.

175. Manufacturer Defendants also worked to discredit or bury negative information. Manufacturer Defendants – often with the help of third-party consultants – targeted a broad range of media to disseminate their message, including negative review articles, letters to the editor, commentaries, case-study reports, and newsletters disparaging reports of the link between opioids and addiction.

176. Manufacturer Defendants' strategies were intended to, and did, knowingly and intentionally distort the truth regarding the risks, benefits and superiority of opioids for chronic pain relief, resulting in distorted prescribing patterns.

b. Key Opinion Leaders

177. Manufacturer Defendants used KOLs (who are generally distinguished physicians and neutral sources of guidance in their medical field), as sources of pro-opioid misinformation for regular practicing doctors, including those in the State of Connecticut who treat residents of the Town of Wallingford.

178. The KOLs have been central to the Manufacturer Defendants' diffuse marketing efforts. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. They have served on

[51] Pamela T.M. Leung, B.Sc. Pharm., *et al*., *A 1980 Letter on the Risk of Opioid Addiction*, 376 NEW ENG. J. MED 2194 (June 1, 2017), http://www.nejm.org/doi/full/10.1056/NEJMc1700150#t=article.

committees that developed treatment guidelines strongly encouraging the use of opioids to treat chronic pain, and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Manufacturer Defendants were able to exert control over each of these modalities through their KOLs.

179. In exchange for these services of the KOLs, Manufacturer Defendants provided them with money, prestige, recognition, research funding, and avenues to publish. This positioned the KOLs to exert even more influence in the medical community.

180. Opioid-makers were not the first to mask their deceptive marketing efforts in purported science. The tobacco industry also used KOLs in its efforts to persuade the public and regulators that tobacco was not addictive or dangerous. For example, tobacco companies funded a research program at Harvard and chose as its chief researcher a doctor who had expressed views in line with industry's views. He was dropped when he criticized low-tar cigarettes as potentially more dangerous, and later described himself as a pawn in the industry's campaign.

181. Manufacturer Defendants cultivated and promoted only those KOLs who could be relied upon to help broaden the chronic pain opioid therapy market. Manufacturer Defendants selected, funded, and elevated those doctors whose public positions were unequivocally supportive of using opioids to treat chronic pain. These doctors' professional reputations were then dependent on continuing to promote a pro-opioid message, even in activities not directly funded by the drug companies.

182. Manufacturer Defendants cited and promoted favorable studies or articles by these KOLs. By contrast, Manufacturer Defendants did not disseminate the publications of doctors critical of the use of chronic opioid therapy. One prominent KOL sponsored by many of the Manufacturer Defendants, Dr. Russell Portenoy, stated that he was told by a drug company

that research critical of opioids (and the doctors who published that research) would never obtain funding.

183. Some KOLs have even gone on to become direct employees and executives of Manufacturer Defendants, like Dr. Haddox, Purdue's Vice President of Health Policy, or Dr. Bradley Galer, Endo's former Chief Medical Officer.

184. Manufacturer Defendants provided substantial opportunities for KOLs to author articles or research studies on topics Manufacturer Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature. As described by Dr. Portenoy, drug companies would approach him with a study that was well under way and ask if he would serve as the study's author. Dr. Portenoy regularly agreed.

185. Manufacturer Defendants also paid KOLs to serve as consultants or on their advisory boards and give talks or present CMEs, often over meals or at conferences. Since 2000, Cephalon, for instance, has paid doctors more than $4.5 million for programs relating to its opioids.

186. Manufacturer Defendants kept close tabs on the content of the misleading materials published by these KOLs. In many instances, they also scripted what these KOLs said – as they did with all their recruited speakers.

187. There was a group of KOLs who received funding and benefits from all the Manufacturer Defendants who participated in an enterprise to pay these KOLs to disseminate misinformation about the safety and efficacy of opioids as a treatment for chronic pain in order to enable the Manufacturer Defendants to unlawfully expand their profits.

188. Dr. Portenoy received research support, counseling fees, and honoraria from Manufacturer Defendants Purdue, Cephalon, Janssen and others. He was also president of the

Front Group American Pain Society ("APS"), and board member of Front Group American Pain Foundation ("APF").

189. Dr. Lynn Webster was the author of numerous CMEs sponsored by Purdue, Cephalon and Endo. He was also president of the Front Group American Academy of Pain Medicine ("AAPM"), and board member of APF.

190. Dr. Scott Fishman was a KOL who authored *Responsible Opioid Prescribing*, a publication sponsored by Manufacturer Defendants Purdue and Cephalon. Dr. Fishman was also a president of APF, and a president of AAPM.

191. Dr. Perry Fine was a KOL who received funding from Manufacturer Defendants Purdue, Cephalon, Janssen and Endo. He was also president of the AAPM, and board member of APF.

c. Continuing Medical Education

192. Physicians are required to attend CMEs in order to keep their medical licenses. Manufacturer Defendants sponsored CMEs and made sure that the content supported their position on opioids. They were thereby able to promulgate their teaching to a large number of doctors that they should be prescribing more opioids.

193. Because CMEs are typically delivered by KOLs who are highly respected in their fields, and are thought to reflect these physicians' medical expertise and "cutting edge" practices, these CMEs can be especially influential to doctors.

194. The countless doctors and other healthcare professionals who participate in accredited CMEs constituted an enormously important audience for opioid reeducation. Manufacturer Defendants targeted general practitioners, who were especially susceptible to Manufacturer Defendants' deceptions because of their lack of specialized training in pain

management and the likelihood that they would treat patients who seek medical treatment for pain management issues.

195. These CMEs, often with names related to treatment of chronic pain, inflated the benefits of opioids, omitted or downplayed their risks, and focused on opioids to the exclusion of alternative treatments.

196. The influence of Manufacturer Defendants' funding on the content of these CMEs is clear. One study by a Georgetown University Medical Center professor compared the messages retained by medical students who reviewed an industry-funded CME article on opioids versus another group who reviewed a non-industry-funded CME article. The industry-funded CME did not mention opioid-related death once; the non-industry-funded CME mentioned opioid-related death 26 times.

197. Students who read the industry-funded article noted more frequently the impression that opioids were underused in treating chronic pain. The "take-aways" of those reading the non-industry-funded CME included the risks of death and addiction much more frequently than those of the other group.

198. Neither group could accurately identify whether the article they read was industry-funded, making clear the difficulty medical practitioners (the audience for CMEs) have in screening and accounting for source bias.[52]

199. By sponsoring CME programs presented by Front Groups like the AAPM, APF, and others, Manufacturer Defendants could expect messages to be favorable to them, as these organizations were financially dependent on Manufacturer Defendants for other projects. The

[52] Adriane Fugh-Berman, *Marketing Messages in Industry-Funded CME*, PHARMEDOUT.ORG (June 25, 2010), http://pharmedout.galacticrealms.com/conference materials.htm.

sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Manufacturer Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids.

d. Treatment Guidelines

200. Manufacturer Defendants produced treatment guidelines for doctors. Such guidelines were crucial for giving legitimacy to extensive opioid prescriptions and providing a framework within which doctors would feel comfortable prescribing them. These guidelines are also cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications.

(i) Federation of State Medical Boards

201. The Federation of State Medical Boards ("FSMB") is an organization representing the various state medical boards in the United States, including the Connecticut Medical Examining Board, which have the power to license doctors, investigate complaints, and discipline physicians. The FSMB finances opioid- and pain-specific programs through grants from Manufacturer Defendants.

202. In 1998, the FSMB developed its *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), which FSMB conceded was produced "in collaboration with pharmaceutical companies." From 1997 to 2013, FSMB received more than $2 million from the Manufacturer Defendants (other than Insys). The FSMB Guidelines taught that opioids were "essential" for treatment of chronic pain, including as a first prescription option. The FSMB Guidelines failed to mention risks relating to respiratory depression and overdose, and discussed addiction only in the sense that "inadequate understanding" of addiction can lead to "inadequate pain control."

203. The publication of *Responsible Opioid Prescribing*, a book adapted from these guidelines, was backed largely by Manufacturer Defendants, including Cephalon, Endo, and Purdue. The FSMB financed the distribution of *Responsible Opioid Prescribing* by its member boards by contracting with drug companies, including Endo and Cephalon, for bulk sales and distribution to sales representatives (for distribution to prescribing doctors). 163,131 copies of *Responsible Opioid Prescribing* were distributed to state medical boards, including the Connecticut Medical Examining Board (and through the boards, to practicing doctors), and the FSMB earned approximately $250,000 in revenue and commissions from their sale.

204. The FSMB Guidelines conveyed the message that "inadequate pain control" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented.

205. Through the FSMB Guidelines, the Manufacturer Defendants were able to turn doctors' fear of discipline on its head – doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught that they would be punished instead if they failed to prescribe opioids to their patients with pain.

(ii) AAPM/APS Guidelines

206. The American Academy of Pain Medicine and the American Pain Society are professional medical societies, each of which received substantial funding from Manufacturer Defendants from 2009 to 2013 (with AAPM receiving well over $2 million).

207. AAPM issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids for treating chronic pain and claimed that

the risk of addiction to opioids was low.[53] The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Purdue, and subsequently became Vice President of Health Policy at Purdue. Dr. Portenoy, one of the main KOLs who received funding from Manufacturer Defendants Janssen, Cephalon, Endo, and Purdue, was the sole consultant. The consensus statement formed the foundation of the FSMB Guidelines. That statement was actively distributed by AAPM until 2012.

208. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines"), continuing to recommend the use of opioids to treat chronic pain.[54] Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy. and Dr. Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue.

209. The AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories.

210. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the AAPM/APS Guidelines were influenced by contributions that drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee members.

211. The AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific

---

53 AAPM & APS, *The Use of Opioids for the Treatment of Chronic Pain*, 6(1) J. OF PAIN 77 (1997), http://www.jpain.org/article/S1082-3174(97)80022-0/pdf.

54 Roger Chou, *et al*., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10(2) THE J. OF PAIN 113-130 (2009), http://www.jpain.org/article/S1526-5900(08)00831-6/abstract.

evidence on opioids. The AAPM/APS Guidelines have been cited 732 times in academic literature, are still available online, and were reprinted in the JOURNAL OF PAIN.

212. Defendants widely referenced and promoted the AAPM/APS Guidelines without disclosing the acknowledged lack of evidence to support them.

(iii) American Geriatrics Society

213. The American Geriatrics Society ("AGS"), a nonprofit organization serving healthcare professionals who work with the elderly, disseminated guidelines regarding the use of opioids for chronic pain in 2002, *The Management of Persistent Pain in Older Persons* (hereinafter "2002 AGS Guidelines"), and 2009, *Pharmacological Management of Persistent Pain in Older Persons* (hereinafter "2009 AGS Guidelines").

214. The 2009 AGS Guidelines recommended that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy" and stated that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."[55] These recommendations are not supported by any study or any other reliable scientific evidence. Nevertheless, they have been cited 278 times in Google Scholar since their 2009 publication.

215. AGS contracted with Manufacturer Defendants Endo, Purdue, and Janssen to disseminate the 2009 AGS Guidelines, and to sponsor CMEs based on them. The Manufacturer Defendants were aware of the content of the 2009 AGS Guidelines when they agreed to provide funding for these projects.

216. The 2009 AGS Guidelines were first published online on July 2, 2009. AGS submitted grant requests to Manufacturer Defendants, including Endo and Purdue, beginning

---

55 *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. AM. GERIATR. SOC'Y 1331, 1339, 1342 (2009), http://onlinelibrary.wiley.com/doi/10.1111/j.1526-4637.2009.00699.x/full.

July 15, 2009. Internal AGS discussions in August 2009 reveal that AGS did not want to receive up-front funding from Manufacturer Defendants, which would suggest drug company influence, but would instead accept commercial support to disseminate the publication. However, by drafting the guidelines knowing that pharmaceutical company funding would be needed, and allowing these companies to determine whether to provide support only after they had approved the message, AGS effectively ceded significant control to these companies. Endo, Janssen, and Purdue all agreed to provide support to distribute the guidelines.

217. Five of ten of the experts on the guidelines panel disclosed financial ties to Manufacturer Defendants, including serving as paid speakers and consultants, presenting CMEs sponsored by Manufacturer Defendants, receiving grants from Manufacturer Defendants, and investing in Manufacturer Defendants' stock.

218. As noted in ¶¶229-30, *infra*, the recommendations (in this case, treatment guidelines) of those organizations not financed by Manufacturer Defendants stood in marked contrast to those financed by the Defendants.

e. Front Groups and Unbranded Advertising

219. Manufacturer Defendants Purdue, Endo, Janssen, and Cephalon collectively used unbranded, third-party marketing (through KOLs and Front Groups) as part of their national marketing strategies for their branded drugs. Unbranded advertising had the dual advantage of having an appearance of independence and credibility, and not being subject to the regulations promulgated by the FDA for branded advertising. The purpose of the FDA regulations on branded advertising, 21 U.S.C. §352(a); 21 C.F.R. §§1.21(a), 202.1(e)(3), 202.1(e)(6), is to encourage truthful advertising.

220. Defendants published print advertisements in a broad array of medical journals, ranging from those geared to a wider audience, such as the JOURNAL OF THE AMERICAN MEDICAL

ASSOCIATION, to those targeted more at specialists, such as the JOURNAL OF PAIN. In 2011 alone, Defendants' advertising budgets exceeded $14 million on the medical journal advertising of opioids, which was nearly three times what they spent in 2001.

221. Manufacturer Defendants Purdue, Cephalon, Janssen, Endo, and Actavis engaged in a series of actions designed to thwart federal advertising guidelines, market themselves by way of seemingly neutral third parties, and appear distanced from these organizations while simultaneously funneling large amounts of money into them. By doing so, they were able to engage in a multi-pronged effort to misrepresent the risks and overstate the benefits of using opioids. These Manufacturer Defendants were also able to change prescribing practices through materials that appeared not to be marketing.

222. One part of this approach was to influence the stances of Front Groups by heavily contributing to the organizations' income. Manufacturer Defendants then turned around and cited materials produced by these groups as evidence of their positions.

(i) The American Pain Foundation's Role as a Front Group for Defendants' Deceptive Marketing

223. APF was a prominent Front Group for Manufacturer Defendants. The group's name is meant to sound official and impartial, but in fact this organization was a front for promotional material and advocacy on behalf of the Manufacturer Defendants.

224. Between 2007 and until its closure in May 2012, APF received upwards of $10 million from Manufacturer Defendants. In 2009 and 2010, it received from them more than 80% of its operating budget. In 2010, for example, APF received more than $1 million from Endo.

225. APF issued "education guides" for patients, policymakers, and the news media that advocated the benefits opioids provided for chronic pain and trivialized their risks, particularly the risk of addiction. APF engaged in a significant multimedia campaign through

television, radio, and the internet to purportedly "educate" patients about their "right" to pain treatment with opioids.

226. The publications available from APF extolled the benefits of opioids, and these publications were underwritten by Manufacturer Defendants Purdue, Cephalon, Janssen, and Endo. For example, one board member published a study in 2010 sponsored by Cephalon, finding that Cephalon's drug Fentora was "generally safe and well-tolerated" in non-cancer patients, even though it was only approved for severe cancer pain.

227. APF held itself out as an independent patient advocacy organization. In reality, APF functioned largely as an advocate for the interests of Defendants, not patients. APF engaged in grassroots lobbying efforts against various legislative initiatives that might limit opioid prescribing, exemplifying APF's true interest which was to make money for the manufacturers, and ignoring patient pain concerns.

228. In practice, APF operated in close collaboration with Manufacturer Defendants. APF submitted grant proposals seeking to fund activities and publications they suggested and assisted in marketing projects for them.

229. APF and APS submitted *amicus* briefs in defense of opioids: in one case, in support of Defendant Purdue Pharma; in another, in support of a doctor on trial for over-prescribing pain medication (who was subsequently found guilty of 16 counts of drug trafficking).

230. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo and others for funding, which also thereby enabled APF to avoid using its line of credit. APF board member, KOL Dr. Portenoy, explained that the lack of funding diversity was one of the biggest problems at APF.

231. All of APF's programs and materials were intended to, and did, reach a national audience, including persons within the Town of Wallingford.

232. A 2012 U.S. Senate Finance Committee investigation between manufacturers and APF resulted in an abrupt halt to this funding. APF's Board dissolved the group within days of this investigation.

(ii) The Role of Other Front Groups in Defendants' Deceptive Marketing

233. AAPM similarly has received more than $2 million from opioid manufacturers since 2009. This group issues treatment guidelines and hosts CME courses, while espousing positions consistent with opioid manufacturers. Presidents of this organization include many of the KOLs mentioned above. A yearly meeting put on by AAPM allows the group to interface with opioid manufacturers, who pay to present "medical education programs" to AAPM and attending doctors.

234. Other Front Groups include the University of Wisconsin Pain & Policy Studies Group, which received $2.5 million from opioid manufacturers to lobby and otherwise promote opioid use; and APS, incorporated in 1977, whose primary corporate supporter is pharmaceutical manufacturer Mallinckrodt Pharmaceuticals.

235. These Front Groups provided important services for the Manufacturer Defendants. They prepared and disseminated unbranded materials promoting the use of opioids to doctors and the public, including by conducting CMEs and issuing treatment guidelines for doctors, and by outreach targeting particularly vulnerable groups such as veterans and elderly people. They also advocated against regulatory guidelines that would limit opioid prescriptions, and responded negatively to journal articles not supporting the use of opioids. The significant

funding and regular interfacing between these sets of organizations ensured that the Front Groups would issue messages supporting the position(s) of the opioid manufacturers.

236. Defendants Purdue, Endo, Janssen, Cephalon, and Actavis collectively exercised substantial control over the content of the messages third parties generated and disseminated, and distributed certain of those materials themselves. These Defendants took an active role in guiding, reviewing, and approving many of the misleading statements issued by these third parties, ensuring that Manufacturer Defendants were consistently aware of their content. By funding, directing, editing, and distributing these materials, Manufacturer Defendants exercised control over their deceptive messages and acted in concert with these third parties to fraudulently promote the use of opioids for the treatment of chronic pain.

237. The behavior and positions of those groups that did not accept funding from manufacturers contrasts significantly with that of the Front Groups. The American Society of Interventional Pain Physicians only recommends high doses of long-acting opioids "in specific circumstances with severe intractable pain" along with "continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvement in physical and functional status and minimal adverse effects."[56]

238. The American College of Occupational and Environmental Medicine similarly discourages "routine use of opioids in the management of patients with chronic pain," though

[56] Laxmaiah Manchikanti, M.D., *et al.*, *Am. Soc'y of Interventional Pain Physicians (ASIPP), guidelines for responsible opioid prescribing in chronic non-cancer pain: Part 1 – evidence assessment*, 15 PAIN PHYSICIAN (Special Issue) S1-S66, https://www.ncbi.nlm.nih.gov/pubmed/22786448; *Part 2 – Guidance*, 15 PAIN PHYSICIAN (Special Issue) S67-S116 (2012), https://www.ncbi.nlm.nih.gov/pubmed/22786449.

conceding that for some patients it may be appropriate.[57] The U.S. Department of Veteran Affairs and the U.S. Department of Defense note risks of abuse and misuse, and "the lack of solid evidence based research on the efficacy of long-term opioid therapy."[58]

f. Defendants Inappropriately Used Their Sales Force and "Speakers Bureaus" to Unfairly and Deceptively Promote Use of Their Drugs

239. Like most drug manufacturers, the Manufacturer Defendants made extensive use of their sales force – sometimes called "detailers," to meet with physician groups one-on-one and promote their products through intimate settings with promotions being advanced by paid speakers. The degree to which the Defendants organized their sales force to "lock-step" sell their products, based on falsehoods and material omissions, is what rendered their marketing efforts unlawful.

240. Defendants' marketing plans, which often operated in parallel to one another, targeted physician groups far afield from pain specialists and anesthesiologists (or cancer doctors) to include physician groups, such as general practice physicians, sports medicine physician groups, etc., with no correlation to the demonstrated needs of the physicians' patients for opioid therapy, or to the risk of abuse.

241. The expanded market of prescribers tended to be, as a group, less informed about opioids and more susceptible to Defendants' marketing. The prescribers included nurse

---

[57] *ACOEM's Guidelines for the Chronic Use of Opioids*, AM. C. OF OCCUPATIONAL & ENVTL. MED. (2011), https://www.nhms.org/sites/default/files/Pdfs/ACOEM%202011-Chronic%20Pain%20Opioid%20.pdf.

[58] The Management of Opioid Therapy for Chronic Pain Working Group, *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain*, U.S. DEP'T OF VETERANS AFFAIRS (May 2010), https://www.va.gov/painmanagement/docs/cpg_opioidtherapy_summary.pdf.

practitioners and physician assistants, who were "share acquisition" opportunities because they were "3x more responsive than MDs to detail," according to an Endo business plan.

242. The expanded market also included internists and general practitioners, with a stated goal, for example, according to an Actavis plan, to move beyond "Kadian loyalists" to an "expanded audience" of "low morphine writers."

243. Each Manufacturer Defendant relied upon "influence mapping," which meant using decile ranking identifying high-volume prescribers so that the Manufacturer's sales force would get the biggest impact from sales calls. Defendants also closely monitored a doctor's prescribing after a sales representative's visit, to allow them to fine-tune their messaging.

244. Each Defendant studiously trained its sales representatives – through detailed action plans, trainings, tests, scripts, role-plays, and supervision tag-alongs – to ensure that the individual sales representatives stayed strictly on script, which involved selling their opioids for off-label uses.

245. In addition to the sales calls, sales representatives were required to identify "product loyalists" – who were high prescribers of drugs – to be selected to be speakers on behalf of the Manufacturer Defendants and be invited to give speeches to their peers proclaiming the effectiveness of the respective Manufacturer's opioid. The speakers were paid handsomely for this service with honoraria ranging from about $800 to $2,000 per program.

246. The Manufacturer Defendants all tracked the effectiveness of the speakers program by monitoring the prescription writing of the attending physicians after the speaker program. It was an effective strategy. Endo noted that "physicians who came into our speaker programs wrote more prescriptions for Opana ER after attending than before."

247. Defendants devoted substantial resources to these direct sales contacts with prescribers. In 2014, Defendants collectively spent $168 million on detailing branded opioids to physicians nationwide. This figure includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Cephalon, $10 million by Endo, and $2 million by Actavis. The total figure is more than double Defendants' collective spending on detailing in 2000. Detailers' role in Defendants' overall promotional efforts was also carefully calibrated; Endo, for example, found that devoting 61% of its marketing budget to sales representatives reflected an "[a]ppropriate combination of personal . . . and non-personal . . . selling initiatives."

248. Defendants spent hundreds of millions of dollars promoting their opioids through their large sales forces, because their monitoring showed that the sales forces' face-to-face meetings with prescribers had a significant influence on prescribing rates. As a routine matter, the Defendants incentivized their sales representatives to sell by basing their compensation on a low salary/high commission format.

249. Upon information and belief, hundreds or thousands of visits from sales representatives from each of the Manufacturer Defendants were made to prescribers in Wallingford and the surrounding area, where the message regarding the use and safety of opioid therapy for the prescribers' patients was untethered from any scientific basis, as the Defendants well knew.

g. Direct-to-Consumer Marketing

250. Manufacturer Defendants targeted patients so that they would ask doctors for those medications specifically. Endo's research, for example, found that such direct-to-consumer communications resulted in greater patient "brand loyalty," with longer durations of Opana ER therapy and fewer discontinuations. Patient-focused advertising, especially direct-to-consumer marketing, is seen by marketing experts within the pharmaceutical industry as substantially

valuable in "increas[ing] market share . . . by bringing awareness to a particular disease that the drug treats."[59] An Actavis marketing plan, for example, noted that "[d]irect-to-consumer marketing affects prescribing decisions."

251. Defendants marketed to consumers through patient-focused "education and support" materials. These took the form of pamphlets, videos, or other publications that patients could view in their physicians' offices. Endo also targeted employer and workers' compensation plan initiatives. This marketing was intended to and did result in patients requesting the opioids in reliance on Defendants' statements that contained falsehoods and material omissions.

252. Defendants also recognized the obstacle that out-of-pocket costs to patients posed to their bottom line sales figures. They overcame this obstacle by providing patients financial assistance with their insurance co-payments, through vouchers and coupons distributed by Defendants' sales representatives when they visited with prescribers. For example, in 2012, Janssen planned to distribute 1.5 million savings cards worth $25 each.

253. Defendant Insys brought the effort to get insurance to pay for its product to an entirely new level of fraud. As the *Fueling an Epidemic* Senate report describes, Insys created a separate department, the Insys Reimbursement Center ("IRC"), that was designed to obtain quick approvals for insurance reimbursement for Insys's product, Subsys, which is an orally administered spray of fentanyl. The IRC unit exercised fraud and deception (such as pretending to be calling from a physician's office, and falsely representing that the prescription was for a cancer patient, which was the only FDA-approved indication for Subsys). The head of the IRC

[59] Kanika Johar, *An Insider's Perspective: Defense of the Pharmaceutical Industry's Marketing Practices*, 76 ALBANY L. REV. 299, 308 (2013), http://www.albanylawreview.org/issues/Pages/article-information.aspx?volume=76&issue=1&page=299.

unit, Elizabeth Guerrieri, pled guilty to "having conspired to defraud insurers" (wire fraud) in June 2017 in the District Court for the District of Massachusetts.

(i) The Elderly

254. Defendants have promoted the unfounded notion that the elderly are particularly unlikely to become addicted to opioids. The 2009 AGS Guidelines, for example, which Purdue, Endo, and Janssen publicized, described the risk of addiction as "exceedingly low in older patients with no current or past history of substance abuse." There is not now, nor has there ever been, any scientifically based evidence to support this statement.

255. On the contrary, a 2010 study examining overdoses among long-term opioid users found that patients 65 or older were among those with the largest number of serious overdoses.[60]

256. Elderly patients taking opioids have been found to be exposed to elevated fracture risks, greater risk for hospitalizations, increased vulnerability to adverse drug effects and interactions, such as respiratory depression, and a significantly higher rate of deaths, heart attacks, and strokes than users of NSAIDs.

257. Defendants' targeted marketing to the elderly, and the absence of cautionary language in their promotional materials, flies in the face of scientific evidence and their own labels, and creates a heightened risk of serious injury to elderly patients.

258. Defendants' efforts have paid off. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59.

---

[60] Kate M. Dunn, *et al.*, *Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study*, ANNALS OF INTERNAL MEDICINE (January 19, 2010), http://annals.org/aim/article-abstract/745518/opioid-prescriptions-chronic-pain-overdose-cohort-study.

(ii) Veterans

259. Veterans, too, were specifically targeted for Defendants' misleading marketing. A 2008 survey showed that prescription drug abuse among military personnel had doubled from 2002 to 2005, and then nearly tripled again over the next three years.[61]

260. In 2009, military doctors wrote 3.8 million prescriptions for narcotic pain pills – four times as many as they had written in 2001. Further, one-third of veterans who were prescribed opioids as of 2012 remained on take-home opioids for more than 90 days. Although many of these veterans are returning from service with traumatic injuries, the increase in opioid prescribing is disproportionate to the population and, in far too many cases, unsuited for their treatment.

261. Among former service members receiving VA services nationally in a single year (2005), 1,013 died of an accidental drug overdose – almost double the rate of the civilian population (19.85 people out of 100,000 per year vs. 10.49 people out of 100,000 per year).[62]

262. Opioids are particularly dangerous to veterans. According to a study published in the 2013 JOURNAL OF AMERICAN MEDICINE, veterans returning from Iraq and Afghanistan who were prescribed opioids have a higher incidence of adverse clinical outcomes, such as overdoses and self-inflicted and accidental injuries; 40% of veterans with post-traumatic stress disorder

---

[61] Research Triangle Institute, *Department of Defense Survey of Health Related Behaviors Among Active Duty Military Personnel* (September 2009), www.dtic.mil/get-tr-doc/pdf?AD=ADA465678.

[62] Amy S.B. Bohnert, Ph.D., et al., *Accidental Poisoning Mortality Among Patients in the Department of Veterans Affairs Health System*, Brief Report, MEDICAL CARE, Vol. 49(4) (April 2011), available at: https://journals.lww.com/lww-medicalcare/Abstract/2011/04000/Accidental_Poisoning_Mortality_Among_Patients_in.11.aspx.

received opioids and benzodiazepines (anti-anxiety drugs) that, when mixed with alcohol, can cause respiratory depression and death.

263. According to a VA Office of Inspector General report, despite the risks, 92.6% of veterans who were prescribed opioid drugs were also prescribed benzodiazepines.[63]

264. As with elderly patients, Defendants both purposefully sought to increase opioid prescribing to this vulnerable group and omitted from their promotional materials the known, serious risks opioids pose to them.

265. *Exit Wounds*, a 2009 publication sponsored by Purdue, distributed by APF with grants from Janssen and Endo, and written as if it were a personal narrative of one veteran, describes opioids as "underused" and the "gold standard of pain medications" and fails to disclose the risk of addiction, overdose, or injury.

266. *Exit Wounds* notes that opioid medications "increase a person's level of functioning" and that "[l]ong experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications."

267. The publication also asserts that "[d]enying a person opioid pain medication because he or she has a history of substance abuse or addiction is contrary to the model guidelines for prescribing opioids, published by the U.S. Federation of State Medical Boards." As laid out above, the FSMB itself received support from Defendants during the time it created and published its guidelines.

---

63 Rept. No. 14-00895-163, Dept. of Veterans Affairs, Office of Inspector General, *Healthcare Inspection – VA Patterns of Dispensing Take-Home Opioids and Monitoring Patients on Opioid Therapy* (May 14, 2014), https://www.va.gov/oig/pubs/VAOIG-14-00895-163.pdf (last visited on Feb. 27, 2018).

268. *Exit Wounds* minimizes the risks of chronic opioid therapy and does not disclose the risk that opioids may have fatal interactions with benzodiazepines, which were taken by a significant number of veterans.[64] The deceptive nature of *Exit Wounds* is obvious when compared to guidance on opioids published by the VA and Department of Defense in 2010 and 2011. The VA's *Taking Opioids Responsibly* describes opioids as "dangerous." It cautions against taking extra doses and mentions the risk of overdose and the dangers of interactions with alcohol. The list of side effects from opioids includes decreased hormones, sleep apnea, hyperalgesia, addiction, immune system changes, birth defects, and death – none of which is mentioned in *Exit Wounds*.

4. Purdue-Specific Misrepresentation: The 12-Hour Dosing Lie

269. In the late 1980s, Purdue (a relatively small pharmaceutical company at the time) was facing a serious revenue threat. Its main drug was a morphine pill for cancer patients with the trade name MS Contin. The patent on MS Contin was about to expire, which meant the drug would face serious downward pricing pressure from generics that were likely to enter the market of an opioid treatment for cancer patients.

270. To solve its "vulnerability of the . . . generic threat," Defendant Purdue decided to devote a huge effort and funding into the launch of another opioid product that it tradenamed OxyContin. OxyContin was classified as an oxycodone similar to Percocet (that was already on

[64] FDA guidance states that materials designed to target a particular audience should disclose risks particular to that audience. *See* FDA Notice, *Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs – Guidance for Industry*, FDA (Aug. 2015), https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm069984.pdf.

the market), but Purdue combined the oxycodone with a time release technique and claimed that the new drug, OxyContin, would control pain for up to 12 hours.

271. Purdue's claim that its opioid could provide 12 hours of pain relief was a primary selling point for its new drug, OxyContin. In its 1992 submission to the United States Patent Office, Purdue touted that OxyContin was a medical breakthrough that controlled pain for 12 hours "in approximately 90% of patients."

272. Armed with its new product, Purdue launched OxyContin in 1996 after obtaining FDA approval in 1995. A Purdue marketing executive stated in a 1995 internal memo (that was obtained by the LOS ANGELES TIMES and reported on in a May 5, 2016 exposé), "[w]e do not want to niche OxyContin just for cancer pain."

273. However, the promise of 12-hour pain relief was not true, which Purdue knew. The effects of OxyContin (both the pain relief and the euphoria) wore off for most of the patients in Purdue's clinical trials well before 12 hours. Many patients would start to crave another dose within eight hours, or even less time.

274. OxyContin tablets provide an initial absorption of approximately 40% of the active medical. This fact causes two results, both of which made OxyContin particularly addictive. First, the initial rush of almost half of the powerful opioid triggers a powerful psychological response. Thus, OxyContin – which is approximately twice as powerful as morphine – acts more like an immediate-release opioid. Second, since there is less of the drug at the end of the 12-hour dosing periods, many patients begin to experience withdrawal symptoms before the 12 hours expire. The combination of fast onset and end-of-dose withdrawal symptoms makes OxyContin powerfully addictive.

275. Although Purdue was well aware of the shorter duration of the drug's effects for many patients, it withheld this information from prescribing physicians and, to the contrary, instructed its sales force (which had ballooned to over 200 by 1997, one year after launch), to recommend to the prescribers that they increase the strength of the dose rather than its frequency.

276. By use of this falsehood, Purdue kept its competitive advantage of being able to claim that OxyContin gives a full 12 hours of relief, allowing the convenience of twice-a-day dosing.

277. This strategy was a triple win for Purdue. First, the maximum strength 80 milligrams of OxyContin netted Purdue more than $630 rather than the $97 for a 10-milligram bottle. Second, if the patient in the throes of opioid withdrawal started to take the drug at shorter intervals, Purdue could claim it was "not their problem." Third, the increased dose made the drug even more addictive, thereby making it likely that Purdue would have a customer for life.

278. To this day, Purdue continues to misrepresent OxyContin to doctors as a 12-hour drug.[65]

279. The LOS ANGELES TIMES exposé stated that, as of 2014, more than 52% of patients taking OxyContin longer than three months were prescribed doses greater than 60

---

[65] PURDUE PHARMA, *Purdue Products: OxyContin® CII (Oxycodone HCI) Extended-Release Tablets* (2017), http://www.purduepharma.com/healthcare-professionals/products/oxycontin/; *OxyContin®: Highlights of Prescribing Information* (Dec. 2016), http://app.purduepharma.com/xmlpublishing/pi.aspx?id=o (OxyContin prescription information); *Medication Guide: OXYCONTIN® (ox-e-KON-tin)(oxycodone hydrochloride) extended-release tablets, CII* (Dec. 2016), http://app.purduepharma.com/xmlpublishing/pi.aspx?id=o&medguide=1 (medication guide); *SETTING THE RECORD STRAIGHT ON OXYCONTIN'S FDA-APPROVED LABEL* (May 5, 2016) (responding to the *Los Angeles Times* article by doubling down on its claims) http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approved-label/ (last visited on Feb. 26, 2018).

milligrams a day. Dr. Debra Houry of the CDC stated in 2017 that those doses were "really concerning" because "the higher you go, the more likely you are to die."

5. Insys-Specific Misrepresentation

280. Insys is the last entrant into the prescription opioid market among the Manufacturer Defendants, having acquired FDA approval for its drug tradenamed Subsys in 2012.

281. As discussed *supra* at ¶75, Subsys is a highly addictive synthetic opioid form of fentanyl mouth-spray approved by the FDA for a very limited indication: treatment of breakthrough cancer pain only in patients who have already been administered other opioids, so they have established a tolerance for opioids.

282. Insys has mounted an aggressive and unlawful off-label marketing strategy for Subsys in violation of the FDCA, 21 U.S.C. §301, *et seq*., knowingly marketing its product for uses that were not approved by the FDA, which led to the submission of false and improper payment requests to government programs Medicare and Medicaid and indictments and/or pleas of many of its key executives.

283. There is a limited customer base for cancer patients who are already taking an opioid to manage cancer pain but who still need an additional boost to treat breakthrough cancer pain. Accordingly, Insys determined to sell its potent and dangerous opioid to a wider class of patients. Their sales force, whose pay was largely dependent on commissions, visited dentists, chiropractors, general practitioners, and others throughout the country, including in Connecticut and the Town of Wallingford and surrounding area, to market Subsys for a wide variety of ailments, from root canals to back pain.

284. The Senate report *Fueling an Epidemic* revealed, among other things, how the Insys sales force was incentivized and indoctrinated to sell Subsys as a safe treatment for many

conditions far afield from breakthrough cancer pain. Moreover – and just as dangerously – the sales staff was instructed to induce their physicians to write prescriptions for higher, more expensive doses.

285. Manufacturer Defendant Insys, and all Individual Defendants, knew that the off-label use of Subsys could be fatal, and, at the very least, could lead to addiction in the user. Despite this knowledge, Manufacturer Defendant Insys unlawfully, recklessly, and with wanton, willful, and criminal intent continued to market its product for the use of innocent persons for whom it was foreseeable that it would cause grave and perhaps fatal harm.

286. On February 10, 2017, the United States Attorney for the District of Connecticut announced that Insys Sales Manager, Jeffrey Pearlman, who was responsible for managing Insys's sales representatives who called on medical prescribers in Connecticut and three other states, paid illegal kickbacks (including $83,500 to one Connecticut physician) to provide Subsys. Pearlman's trial is expected to convene in September 2018 in federal court in New Haven, *U.S. v. Pearlman*, No. 3:17-cr-00027 (D. of Conn.).

287. A nurse, Heather Alfonso, formerly employed by the Comprehensive Pain and Headache Treatment Center in Derby, Connecticut, pled guilty in June 2015 to a federal indictment of accepting kickbacks from Insys to prescribe Subsys, often to non-cancer patients. Natalie Levine, a former Insys Connecticut-based salesperson who is married to a former CEO of Insys, pled guilty in July 2017 in federal court in Hartford for violating the federal anti-kickback statute by bribing nurse Heather Alfonso through a sham speakers bureau to prescribe Subsys for patients who did not have cancer.

6. Actavis-Specific Misrepresentation

288. Actavis distributed a product advertisement that claimed that use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and mental

health," and cause patients to enjoy their lives. The FDA warned Actavis that such claims were misleading, disclaiming: "We are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect the drug has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in an overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[66]

289. Actavis disregarded the FDA's 2010 warning and Actavis sales representatives continued to market the falsehood that prescribing Actavis's opioids would improve patients' ability to function and improve their quality of life.

290. Actavis's sale training modules severely downplayed the association of Kadian and other opioids as to the risk of addiction. A 2010 module represented that "there is no evidence that simply taking opioids for a period of time will cause substance abuse or addiction" and, instead "[i]t appears likely that most substance-abusing patients in pain management practices have an abuse problem before entering the practice." Not only did Actavis falsely suggest the low likelihood of addiction in patients, but also shifted culpability to the patients, the same people they were entrusted to treat.

[66] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf.

7. Guilty Pleas and Prior Attorney General Settlements with Certain Defendants in Connection with Improper Opioid Marketing

a. Purdue's 2007 Guilty Plea for OxyContin Marketing Misrepresentations

291. In 2007, Purdue and three top executives were indicted in federal court in Virginia and pled guilty to fraud in promoting OxyContin as non-addictive and appropriate for chronic pain.

292. As part of its guilty plea, Purdue admitted that:

> Beginning on or about December 12, 1995, and continuing until on or about June 30, 2001, certain PURDUE supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications, as follows:
>
> * * *
>
> b. [Purdue] told Purdue sales representatives they could tell health care providers that OxyContin potentially creates less chance for addiction than immediate-release opioids;
>
> c. [Purdue] sponsored training that taught PURDUE sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids;
>
> d. [Purdue] told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug; and
>
> e. [Purdue] told certain health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.[67]

[67] https://archive.org/stream/279028-purdue-guilty-plea/279028-purdue-guilty-plea_djvu.txt.

293. Under the plea agreement, Purdue agreed to pay $600 million in criminal and civil penalties – one of the largest settlements in history for a drug company's marketing misconduct.[68] Also, Purdue's Chief Executive Officer, General Counsel, and Chief Medical Officer pled guilty and agreed to pay a total of $34.5 million in penalties.[69]

294. Even after this plea, Purdue's wrongdoing continued, including its improper marketing campaign, which, along with the other Manufacturer Defendants, conditioned physicians to believe that opioids were safe and effective treatments for the long-term treatment of chronic pain.

295. Purdue made many subsequent misleading statements regarding its own opioid products and opioids generally, continuing long after its 2007 guilty plea as alleged herein.

b. Cephalon Enters a Criminal Plea for Off-Label Marketing of Actiq.

296. The FDA approved the powerful Fentanyl drug, Actiq, that was in the form of a lollipop for use only in opioid-tolerant cancer patients (meaning those patients for whom morphine-based painkillers were no longer effective).

297. From 2001 through at least 2006, Cephalon, the manufacturer of Actiq, promoted the drug for non-cancer patients to use for such maladies as migraines, sickle-cell pain crises, and injuries, and in anticipation of changing wound dressings or radiation therapy. Cephalon also promoted Actiq for use in patients who were not opioid-tolerant, and for whom the drug could be fatal.

---

68 *Id*.

69 *Id*.

298. Using the mantra "pain is pain," Cephalon instructed the Actiq sales representatives to focus on physicians other than oncologists, including general practitioners, and to promote the drug for many ordinary types of pain.

299. Cephalon was charged in a criminal violation with off-label selling of Actiq and two of its other drugs, by the United States Attorney in the Eastern District of Pennsylvania. In a plea agreement with the U.S entered into in September 2008, Cephalon agreed to pay $50 million in settlement of the off-label marketing charges and, in a separate civil agreement, it agreed to pay $375 million plus interest to resolve False Claims Act charges arising from the off-label selling.

300. Acting U.S. Attorney Laurie Magid stated:

> These are potentially harmful drugs that were being peddled as if they were, in the case of Actiq, actual lollipops instead of a potent pain medication intended for a specific class of patients. . . . This company subverted the very process put in place to protect the public from harm, and put patients' health at risk for nothing more than boosting its bottom line. People have an absolute right to their doctors' best medical judgment. They need to know the recommendations a doctor makes are not influenced by sales tactics designed to convince the doctor that the drug being prescribed is safe for uses beyond what the FDA has approved.[70]

c. Purdue's 2015 Settlement with the New York Attorney General

301. On August 19, 2015, the New York Attorney General ("NYAG") entered into a settlement agreement with Purdue regarding Purdue's marketing of opioids.

302. In the settlement agreement, the NYAG noted that, from at least March 2014 to March 2015, the Purdue website www.inthefaceofpain.com failed to disclose that doctors who provided testimonials on the site were paid by Purdue. The NYAG concluded that Purdue's

[70] Press Release, U.S. Dept. of Justice, U.S. Attorney, Eastern District of Pennsylvania, *Pharmaceutical Company Cephalon to Pay $425 Million for Off-Label Drug Marketing* (Sept. 29, 2008), *https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html.*

failure to disclose these financial connections misled consumers regarding the objectivity of the testimonials.

303. The settlement agreement stated, in relevant part:

> Purdue maintains an unbranded pain management advocacy website, www.inthefaceofpain.com. From March 2014 to March 2015, the website received a total of 251,648 page views. Much of the video content on www.inthefaceofpain.com is also available on YouTube. . . .
>
> Written and video testimonials from several dozen "Advocates," whose faces appear on the website and many of whom are HCPs [health care providers], comprise a central component of the site. For example, Dr. Russell Portenoy, the recipient of almost $4,000 from Purdue for meeting and travel costs, was quoted on the website as follows: "The negative impact of unrelieved pain on the lives of individuals and their families, on the healthcare system, and on society at large is no longer a matter of debate. The unmet needs of millions of patients combine into a major public health concern. Although there have been substantive improvements during the past several decades, the problem remains profound and change will require enormous efforts at many levels. Pressure from patients and the larger public is a key element in creating momentum for change."
>
> Although Purdue created the content on www.inthefaceofpain.com . . . the site creates the impression that it is neutral and unbiased. . . .
>
> ***Purdue's failure to disclose its financial connections with certain Advocates has the potential to mislead consumers by failing to disclose the potential bias of these individuals***.[71]

[Emphasis added].

304. As part of the settlement, Purdue agreed to make certain disclosures on www.inthefaceofpain.com and its similar websites, and to pay a monetary penalty.[72]

---

[71] Settlement Agreement between New York Attorney General and Purdue Pharma at 7-8 (Aug. 19, 2015) ("NYAG-Purdue Settlement Agreement"), https:/ag.ny.gov/pdfs/Purdue-AOD-Executed.pdf.

[72] *Id.* at 15-17.

305. Again, however, Purdue's improper marketing of opioids has continued, following its prior regulatory settlements, all as alleged more fully herein. An October 30, 2017 article in THE NEW YORKER states in pertinent part:

> Purdue has continued to fight aggressively against any measures that might limit the distribution of OxyContin, in a way that calls to mind the gun lobby's resistance to firearm regulations. Confronted with the prospect of modest, commonsense measures that might in any way impinge on the prescribing of painkillers, Purdue and its various allies have responded with alarm, suggesting that such steps will deny law-abiding pain patients access to medicine they desperately need. Mark Sullivan, a psychiatrist at the University of Washington, distilled the argument of Purdue: "Our product isn't dangerous – it's *people* who are dangerous."[73]

[Emphasis in original].

306. Further, according to that article, Purdue has continued to search for new users through the present, both domestically and now increasingly overseas, and in August 2015, even sought to market OxyContin to children as young as 11.[74]

d. Endo's 2016 Settlement with the New York Attorney General

307. On March 1, 2016, the NYAG entered into a settlement agreement with Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. regarding Endo's marketing and sales of Opana ER.

308. On Endo's website www.opana.com, Endo claimed, until at least April 2012, that "[m]ost healthcare providers who treat patients with pain agree that patients treated with

---

[73] Patrick Radden Keefe, *The Family That Built an Empire of Pain*, THE NEW YORKER (Oct. 30, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain.

[74] *Id*.

prolonged opioid medicines usually do not become addicted."[75] The NYAG found that Endo had no evidence for that statement.[76]

309. Endo also provided training materials to its sales representatives stating that addiction to opioids is not common, and that "symptoms of withdrawal do not indicate addiction."[77] The NYAG found that those statements were unwarranted.[78]

310. Endo also trained its sales representatives to distinguish addiction from "pseudoaddiction." ***The NYAG found that "the 'pseudoaddiction' concept has never been empirically validated*** and in fact has been abandoned by some of its proponents," all as alleged above.[79] [Emphasis added].

311. The NYAG also noted that Endo omitted information about certain studies in its marketing pamphlets distributed to health care providers, and that Endo "omitted . . . adverse events from marketing pamphlets."[80]

312. As part of the NYAG settlement, Endo paid a $200,000 penalty and agreed to refrain from doing the following in New York: (i) "make statements that Opana ER or opioids generally are non-addictive," (ii) "make statements that most patients who take opioids do not become addicted" and (iii) "use the term 'pseudoaddiction' in any training or marketing."[81]

---

75 Settlement Agreement between New York Attorney General and Endo, ¶20 (March 1, 2016) ("NYAG-Endo Settlement Agreement"), https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

76 *Id*.

77 *Id.*, ¶22.

78 *Id*.

79 *Id.*, ¶23.

80 *Id.*, ¶30.

81 *Id.*, ¶41.

e. Mallinckrodt's 2017 Settlement with the DEA and U.S. Attorneys

313. In 2008, the DEA and federal prosecutors launched an investigation into Mallinckrodt, charging that the company ignored red flags and supplied – and failed to report – suspicious orders for its generic oxycodone between 2008 and 2012.[82] The U.S. Attorney's office in Detroit handled the case. The investigation uncovered that from 2008 to 2012, Mallinckrodt sent, for example, 500 million tablets of oxycodone into a single state, Florida – "66 percent of all oxycodone sold in the state."[83] According to the internal government documents obtained by the Washington Post, Mallinckrodt's failure to report could have resulted in "nearly 44,000 federal violations and exposed it to $2.3 billion in fines."[84]

314. Despite learning from the DEA that generic opioids seized in a Tennessee drug operation were traceable to one of its Florida distributors, Sunrise Wholesale ("Sunrise"), Mallinckrodt in the following six weeks sent 2.1 million tablets of oxycodone to Sunrise. In turn, Sunrise sent at least 92,400 oxycodone tablets to a single doctor over an 11-month period, who, in one day, prescribed 1,000 tablets to a single patient.[85]

315. According to documents obtained by the *Washington Post*, investigators also found "scores of alleged violations" at Mallinckrodt's plant in Hobart, New York. Those

---

82 Lenny Bernstein & Scott Higham, *The government's struggle to hold opioid manufacturers accountable*, Wash. Post (Apr. 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.7ce8c975dd86.

83 *Id.*

84 *Id.*

85 *Id.*

violations included the failure to keep accurate records, to document transfers of drugs and to secure narcotics.[86]

316. During the DEA's investigation, Mallinckrodt sponsored the HDA (known as the Healthcare Distribution Management Association until 2016), an industry-funded organization that represents pharmaceutical distributors.[87] The HDA initiated the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 (enacted April 19, 2016), which requires the DEA to give notice of violation and an opportunity to comply, to pharmacies and distributors, before withdrawing licenses. This Act substantially weakened the DEA's ability to regulate manufacturers and wholesalers.[88]

317. In May 2014, Mallinckrodt posted a video titled "Red Flags: Pharmacists Anti-Abuse Video." The video is a thinly veiled attempt to divert responsibility for the opioid epidemics away from manufacturers and wholesalers, and toward individual pharmacists. The video was sponsored by the Anti-Diversion Industry Working Group, which is composed of Cardinal Health, Actavis, McKesson, Mallinckrodt, AmerisourceBergen, and Qualitest (a part of Endo)—all of whom are also missing from the list of those responsible.[89]

318. In April 2017, Mallinckrodt reached an agreement with the DEA and the U.S. Attorneys for the Eastern District of Florida and Northern District of New York to pay $35

---

86 *Id.*

87 *Sponsors: HDA's Annual Circle Sponsors*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/hda-sponsors (last visited Dec. 11, 2017).

88 Chris McGreal, *Opioid epidemic: ex-DEA official says Congress is protecting drug makers*, Guardian (Oct. 31, 2016, 9:26 EDT), https://www. theguardian.com/us-news/2016/oct/31/opioidepidemic-dea-official-congress-big-pharma.

89 Mallinckrodt Pharmaceuticals, *Red Flags: Pharmacists Anti-Abuse Video*, YouTube (May 27, 2014), https://www.youtube.com/watch?v=fdv0B210bEk&t=1s.

million to resolve a probe of its distribution of its opioid medications.[90] Mallinckrodt finalized the settlement on July 11, 2017, agreeing to pay $35 million while admitting no wrongdoing.[91]

8. Summary of Manufacturer Defendants' Unlawful Marketing Claims and Practices

Purdue	**Falsehood that scientific evidence supports the long-term use of opioids to improve patients' function and quality of life** a. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals titled "Pain vignettes," which were case studies featuring patients, each with pain conditions persisting over several months, recommending OxyContin for each. One such patient, "Paul," is described to be a "54-year old writer with osteoarthritis of the hands," and the vignettes imply that an OxyContin prescription will help him work more effectively. b. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The sole reference for the functional improvement claim noted the absence of long-term studies and actually stated: "For functional outcomes, the other analgesics were significantly more effective than were opioids." The *Policymaker's Guide* is still available online. c. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids, when used properly, "give [pain patients] a quality of life we deserve." APF distributed 17,200 copies in one year alone, according to its 2007 Annual Report, and the guide currently is available online. d. Purdue sponsored APF's *Exit Wounds* (2009), which taught veterans that opioid medications "increase your level of functioning." *Exit Wounds* also omits warnings of the risk of interactions between opioids

[90] Linda A. Johnson, *Mallinckrodt to Pay $35M in Deal to End Feds' Opioid Probe*, U.S. News & World Report (Apr. 3, 2017, 6:47 PM), https://www.usnews.com/news/business/articles/2017-04-03/mallinckrodt-to-pay-35m-in-deal-to-end-feds-opioid-probe.

[91] Press Release, U.S. Department of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

	and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder. e. Purdue sponsored the FSMB's *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." Purdue also spent over $100,000 to support distribution of the book. f. Purdue sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life. On information and belief, these deceptive representations were made to practitioners in the Wallingford area. **Defendant misrepresents the risk of addiction** a. Purdue published a prescriber and law enforcement education pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which under the heading, "Indications of Possible Drug Abuse," shows pictures of the stigmata of injecting or snorting opioids – skin popping, track marks, and perforated nasal septa. In fact, opioid addicts who resort to these extremes are uncommon; the far more typical reality is patients who become dependent and addicted through oral use. Thus, these misrepresentations wrongly reassure doctors that as long as they do not observe those signs, they need not worry that their patients are abusing or addicted to opioids. b. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that less than 1% of children prescribed opioids will become addicted. This publication is still available online. This publication also asserted that pain is undertreated due to "misconceptions about opioid addiction." c. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which asserted that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft. d. A Purdue-funded study with a Purdue co-author claimed that "evidence that the risk of psychological dependence or addiction is low in the absence of a history of substance abuse."[92] The study relied only on the 1980 Porter-Jick letter to the editor concerning a chart review of hospitalized patients, not patients taking Purdue's long-acting, take-

[92] C. Peter N. Watson, *et al.*, *Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial in painful diabetic neuropathy*, PAIN 105, 71-78 (March 31, 2003).

	home opioid. Although the term "low" is not defined, the overall presentation suggests the risk is so low as not to be a worry. e. Purdue contracted with AGS to produce a CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. These guidelines falsely claim that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." None of the references in the guidelines corroborates the claim that elderly patients are less likely to become addicted to opioids, and the claim is, in fact, untrue. Purdue was aware of the AGS guidelines' content when it agreed to provide this funding, and AGS drafted the guidelines with the expectation it would seek drug company funding to promote them after their completion. f. APF's *Exit Wounds* (2009), sponsored by Purdue, counseled veterans that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." Although the term "very unlikely" is not defined, the overall presentation suggests it is so low as not to be a worry. g. Purdue sales representatives told prescribers that its drugs were "steady state," the implication of which was that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused. On information and belief, these deceptive representations were made to practitioners in the Wallingford area. h. Purdue sales representatives told prescribers that Butrans has a lower abuse potential than other drugs because it was essentially tamperproof and, after a certain point, patients no longer experience a "buzz" from increased dosage. On information and belief, these deceptive representations were made to practitioners in the Wallingford area. i. Advertisements that Purdue sent to prescribers stated that OxyContin ER was less likely to be favored by addicts, and, therefore, less likely to be abused or diverted, or result in addiction. On information and belief, these deceptive representations were made to practitioners in the Wallingford area. j. In discussions with prescribers, Purdue sales representatives omitted discussion of addiction risks related to Purdue's drugs. On information and belief, these material omissions were made in presentations to practitioners in the Wallingford area. **Defendant deceptively claimed without scientific support that the risk of addiction could be avoided or managed** a. Purdue's unbranded website, *In the Face of Pain* (inthefaceofpain.com), states that policies that "restrict[] access to patients with pain who also have a history of substance abuse" and

	"requiring special government-issued prescription forms for the only medications that are capable of relieving pain that is severe" are "at odds with" best medical practices.[93] b. Purdue sponsored a 2012 CME program titled *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. This presentation recommended that use of screening tools, more frequent refills, and switching opioids could treat a high-risk patient showing signs of potentially addictive behavior. c. Purdue sponsored a 2011 webinar taught by KOL Dr. Lynn Webster, titled *Managing Patients' Opioid Use: Balancing the Need and Risk*. This publication taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths." d. Purdue sales representatives told prescribers that screening tools can be used to select patients appropriate for opioid therapy and to manage the risks of addiction. On information and belief, these false representations were made to practitioners in the Wallingford area. **Defendant falsely stated or suggested the concept of "pseudoaddiction" and patients who only need more opioids, and should be treated as such** a. Purdue published a prescriber and law enforcement education pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that "emerged in the literature to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated." b. Purdue distributed to physicians at least as of November 2006, and posted on its unbranded website, *Partners Against Pain*, a pamphlet copyrighted in 2005 and titled *Clinical Issues in Opioid Prescribing*. This pamphlet included a list of conduct including "illicit drug use and deception," which it defined as indicative of pseudoaddiction or untreated pain. It also states: "Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when ***pain is undertreated***. . . . Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be ***distinguished from true addiction*** in that the behaviors resolve

[93] *See In the Face of Pain Fact Sheet: Protecting Access to Pain Treatment*, Purdue Pharma L.P. (Resources verified Mar. 2012), www.inthefaceofpain.com/content/uploads/2011/12/factsheet_ProtectingAccess.pdf.

	when the pain is effectively treated." (Emphasis added). c. Purdue sponsored FSMB's *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction. Purdue also spent over $100,000 to support distribution of the book. d. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which states: "Pseudo-addiction describes patient behaviors that may occur when ***pain is undertreated***. . . . Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated." (Emphasis added). **Defendant falsely stated or suggested that withdrawal from opioids was not a problem and prescribing or using opioids should be without hesitation** a. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but did not disclose the significant hardships that often accompany cessation of use. b. Purdue sales representatives told prescribers that the effects of withdrawal from opioid use can be successfully managed. On information and belief, these false representations were made to practitioners in the Wallingford area. c. Purdue sales representatives told prescribers that the potential for withdrawal on Butrans was low due to Butrans's low potency and its extended release mechanism. On information and belief, these false representations were made to practitioners in the Wallingford area. **Defendant suggested that high-dose opioid therapy was safe** a. Purdue's *In the Face of Pain* website, along with initiatives of APF, promoted the notion that if a patient's doctor does not prescribe them what – in their view – is a sufficient dose of opioids, they should find another doctor who will. In so doing, Purdue exerted undue, unfair, and improper influence over prescribers who face pressure to accede to the resulting demands. b. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dose escalations are "sometimes necessary," even indefinitely high ones, which suggested that high-dose opioids are safe and appropriate and did not disclose the risks from high-dose opioids. This publication is still available online.

	c. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The guide also claimed that some patients "need" a larger dose of the drug, regardless of the dose currently prescribed. This language fails to disclose heightened risks at elevated doses. d. Purdue sponsored a CME issued by the American Medical Association in 2003, 2007, 2010, and 2013. The CME, *Overview of Management Options*, was edited by KOL Dr. Russell Portenoy, among others, and taught that other drugs, but not opioids, are unsafe at high doses. The 2013 version is still available for CME credit. e. Purdue sales representatives told prescribers that opioids were just as effective for treating patients long-term and omitted any discussion that increased tolerance would require increasing, and increasingly dangerous, doses. On information and belief, these deceptive representations were made to practitioners in the Wallingford area. **Defendant deceptively omitted the risks of opioids, including in comparison to NSAIDs** a. Purdue sponsored APF's *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. b. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which advised patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributes 10,000 to 20,000 deaths annually to NSAID overdose. *Treatment Options* also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. c. Purdue sponsored a CME issued by the American Medical Association in 2003, 2007, 2010, and 2013, and the 2013 version is still available for CME credit. The CME, *Overview of Management Options*, was edited by KOL Dr. Russell Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses. d. Purdue sales representatives told prescribers that NSAIDs were more toxic than opioids. On information and belief, these false representations were made to practitioners in the Wallingford area.
Cephalon	**Falsehood that scientific evidence supports the long-term use of opioids to improve patients' function and quality of life** a. Cephalon sponsored the FSMB's *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional

	improvement as the goal of a "long-term therapeutic treatment course." Cephalon also spent $150,000 to purchase copies of the book in bulk and distributed the book through its pain sales force to 10,000 prescribers and 5,000 pharmacists. b. Cephalon sponsored the APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids when used properly "give [pain patients] a quality of life we deserve." The *Treatment Options* guide notes that non-steroidal anti-inflammatory drugs have greater risks with prolonged duration of use, but there was no similar warning for opioids. APF distributed 17,200 copies in one year alone, according to its 2007 annual report, and the publication is currently available online. c. Cephalon sponsored a CME written by KOL Dr. Lynn Webster, titled *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC from September 28, 2007, through December 15, 2008. The CME taught that Cephalon's Actiq and Fentora improve patients' quality of life and allow for more activities when taken in conjunction with long-acting opioids. d. Cephalon sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life. On information and belief, these false representations were made to practitioners in the Wallingford area. **Defendant misrepresented the risk of addiction** a. Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient's Guide*, which claims, among other things, that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids." b. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft. c. In discussions with prescribers, Cephalon sales representatives omitted any discussion of addiction risks related to Cephalon's drugs. On information and belief, these deceptive representations were made to practitioners in the Wallingford area. **Defendant deceptively claimed without scientific support that the risk of addiction could be avoided or managed** a. Cephalon sponsored APF's *Treatment Options: A Guide for People*

	Living with Pain (2007), which taught patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed." **Defendant falsely stated or suggested the concept of "pseudoaddiction" and patients who only need more opioids, and should be treated as such** a. Cephalon sponsored FSMB's *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding are all signs of pseudoaddiction. Cephalon also spent $150,000 to purchase copies of the book in bulk and distributed it through its pain sales force to 10,000 prescribers and 5,000 pharmacists. **Defendant suggested that high-dose opioid therapy was safe** a. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of their opioid, regardless of the dose currently prescribed. b. Cephalon sponsored a CME written by KOL Dr. Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids that include aspirin and acetaminophen are less effective to treat breakthrough pain because of dose limitations. c. Cephalon sales representatives assured prescribers that opioids were safe, even at high doses. On information and belief, these false representations were made to practitioners in the Wallingford area. **Defendant deceptively omitted the risks of opioids, including in comparison to NSAIDs** a. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributed 10,000 to 20,000 deaths annually to NSAID overdose. *Treatment Options* also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. b. Cephalon sales representatives told prescribers that NSAIDs were more toxic than Cephalon's opioids. On information and belief, these

	false representations were made to practitioners in the Wallingford area.
Janssen	**Falsehood that scientific evidence supports the long-term use of opioids to improve patients' function and quality of life** a. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. On the cover, this guide features a man playing golf and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. The guide states as a "fact" that "opioids may make it *easier* for people to live normally" (emphasis in the original). The myth/fact structure implies authoritative backing for the claim that does not exist. The targeting of older adults also ignored heightened opioid risks in this population. b. Janssen sponsored, developed, and approved content of a website, *Let's Talk Pain* in 2009, acting in conjunction with the APF, AAPM, and ASPMN, whose participation in *Let's Talk Pain* Janssen financed and orchestrated. This website featured an interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," inaccurately implying her experience would be representative. c. Janssen provided grants to APF to distribute *Exit Wounds* to veterans, which taught that opioid medications "*increase* your level of functioning" (emphasis in the original). *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder. d. Janssen sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life by helping them become more physically active and return to work. On information and belief, these false representations were made to practitioners in the Wallingford area. **Defendant misrepresents the risk of addiction** a. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and which its sales force distributed. This guide described a "myth" that opioids are addictive, and asserts as fact that "[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain." Although the term "rarely" is not defined, the overall presentation suggests the risk is so

	low as not to be a worry. The language also implies that as long as a prescription is given, opioid use is not a problem. b. Janssen contracted with AGS to produce a CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. These guidelines falsely claim that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." The study supporting this assertion does not analyze addiction rates by age and, as already noted, addiction remains a significant risk for elderly patients. Janssen was aware of the AGS guidelines' content when it agreed to provide this funding, and AGS drafted the guidelines with the expectation it would seek drug company funding to promote them after their completion. c. Janssen provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." Although the term "very unlikely" is not defined, the overall presentation suggests the risk is so low as not to be a worry. d. Janssen currently runs a website, *PrescribeResponsibly.com* (last modified July 2, 2015), which claims that concerns about opioid addiction are "overstated." e. A June 2009 Nucynta Training module warns Janssen's sales force that physicians are reluctant to prescribe controlled substances like Nucynta, but this reluctance is unfounded because "the risks . . . are much smaller than commonly believed." f. Janssen sales representatives told prescribers that its drugs were "steady state," the implication of which was that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused. On information and belief, these deceptive representations were made to practitioners in the Wallingford area. g. Janssen sales representatives told prescribers that Nucynta and Nucynta ER were "not opioids," implying that the risks of addiction and other adverse outcomes associated with opioids were not applicable to Janssen's drugs. In truth, however, as set out in Nucynta's FDA-mandated label, Nucynta "contains tapentadol, an opioid agonist and Schedule II substance with abuse liability similar to other opioid agonists, legal or illicit." On information and belief, these false representations were made to practitioners in the Wallingford area. h. Janssen sales representatives told prescribers that Nucynta's unique properties eliminated the risk of addiction associated with the drug. On information and belief, these false representations were made to

	practitioners in the Wallingford area. i. In discussions with prescribers, Janssen sales representatives omitted discussion of addiction risks related to Janssen's drugs. On information and belief, these deceptive representations were made to practitioners in the Wallingford area. **Defendant falsely stated or suggested the concept of "pseudoaddiction" and patients who only need more opioids, and should be treated as such** a. Janssen's website, *Let's Talk Pain*, stated from 2009 through 2011 that "pseudoaddiction . . . refers to patient behaviors that may occur when ***pain is under-treated***" and "[p]seudoaddiction is ***different from true addiction*** because such behaviors can be resolved with effective pain management." (Emphasis added). **Defendant falsely stated or suggested that withdrawal from opioids was not a problem and prescribing or using opioids should be without hesitation** a. A Janssen PowerPoint presentation used for training its sales representatives, titled "Selling Nucynta ER," indicates that the "low incidence of withdrawal symptoms" is a "core message" for its sales force. This message is repeated in numerous Janssen training materials between 2009 and 2011. The studies supporting this claim did not describe withdrawal symptoms in patients taking Nucynta ER beyond 90 days, or at high doses, and would therefore not be representative of withdrawal symptoms in the chronic pain population. Patients on opioid therapy long-term and at high doses will have a harder time discontinuing the drugs and are more likely to experience withdrawal symptoms. In addition, in claiming a low rate of withdrawal symptoms, Janssen relied upon a study that only began tracking withdrawal symptoms in patients two to four days after discontinuing opioid use, when Janssen knew or should have known that these symptoms peak earlier than that for most patients. Relying on data after that initial window painted a misleading picture of the likelihood and severity of withdrawal associated with chronic opioid therapy. Janssen also knew or should have known that the patients involved in the study were not on the drug long enough to develop rates of withdrawal symptoms comparable to rates of withdrawal suffered by patients who use opioids for chronic pain—the use for which Janssen promoted Nucynta ER. b. Janssen sales representatives told prescribers that patients on Janssen's drugs were less susceptible to withdrawal than those on other opioids. On information and belief, these false representations were made to practitioners in the Wallingford area.

	Defendant suggested that high-dose opioid therapy was safe a. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. This guide listed dose limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased doses from opioids. The publication also falsely claimed that it is a "myth" that "opioid doses have to be bigger over time."
Endo	**Falsehood that scientific evidence supports the long-term use of opioids to improve patients' function and quality of life** a. Endo sponsored a website, painknowledge.com, through APF and the National Initiative of Pain Control ("NIPC"), which claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it. b. A CME sponsored by Endo, titled *Persistent Pain in the Older Patient*, taught that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." c. Endo distributed handouts to prescribers that claimed that use of Opana ER to treat chronic pain would allow patients to perform work as a chef. This flyer also emphasized Opana ER's indication without including equally prominent disclosure of the "moderate to severe pain" qualification.[94] d. Endo's sales force distributed FSMB's *Responsible Opioid Prescribing* (2007). This book taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." e. Endo provided grants to APF to distribute *Exit Wounds* to veterans, which taught that opioid medications "*increase* your level of functioning" (emphasis in the original). *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic

[94] FDA regulations require that warnings or limitations be given equal prominence in disclosure, and failure to do so constitutes "misbranding" of the product. 21 C.F.R. §202.1(e)(3); *see also* 21 U.S.C. §331(a).

	stress disorder. e. Endo sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life by helping them become more physically active and return to work. On information and belief, these false representations were made to practitioners in the Wallingford area. **Defendant misrepresented the risk of addiction** a. Endo trained its sales force in 2012 that use of long-acting opioids resulted in increased patient compliance, without any supporting evidence. b. Endo's advertisements for the 2012 reformulation of Opana ER claimed it was ***designed to be crush resistant***, in a way that conveyed that it was less likely to be abused. This claim was false; the FDA warned in a May 10, 2013 letter that there was no evidence Endo's design "would provide a reduction in oral, intranasal or intravenous abuse" and Endo's "postmarketing data submitted are insufficient to support any conclusion about the overall or route-specific rates of abuse." Further, Endo instructed its sales representatives to repeat this claim about "design," with the intention of conveying Opana ER was less subject to abuse. c. Endo sponsored a website, painknowledge.com, through APF and NIPC, which claimed in 2009 that: "[p]eople who take opioids as prescribed usually do not become addicted." Although the term "usually" is not defined, the overall presentation suggests the risk is so low as not to be a worry. The language also implies that as long as a prescription is given, opioid use will not become problematic. Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it. d. Endo sponsored a website, PainAction.com, which stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." e. Endo sponsored CMEs published by APF and NIPC, of which Endo was the sole funder, titled *Persistent Pain in the Older Adult* and *Persistent Pain in the Older Patient*. These CMEs claimed that opioids used by elderly patients present "possibly less potential for abuse than in younger patients[,]" which statement lacks evidentiary support and deceptively minimizes the risk of addiction for elderly patients. f. Endo distributed an education pamphlet with the Endo logo titled *Living with Someone with Chronic Pain*, which inaccurately minimized the risk of addiction: "Most health care providers who treat people with

	pain agree that most people do not develop an addiction problem." g. Endo distributed a patient education pamphlet edited by KOL Dr. Russell Portenoy titled *Understanding Your Pain: Taking Oral Opioid Analgesics*. It claimed that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems." This implies that pain patients prescribed opioids will not become addicted, which is unsupported and untrue. h. Endo contracted with AGS to produce a CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. These guidelines falsely claim that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." None of the references in the guidelines corroborates the claim that elderly patients are less likely to become addicted to opioids, and there is no such evidence. Endo was aware of the AGS guidelines' content when it agreed to provide this funding, and AGS drafted the guidelines with the expectation it would seek drug company funding to promote them after their completion. i. Endo sales representatives told prescribers that its drugs were "steady state," the implication of which was that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused. On information and belief, these false representation were made to practitioners in the Wallingford area. j. Endo provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." Although the term "very unlikely" is not defined, the overall presentation suggests that the risk is so low as not to be a worry. k. In discussions with prescribers, Endo sales representatives omitted discussion of addiction risks related to Endo's drugs. On information and belief, these material omissions were made in representations to practitioners in the Wallingford area. **Defendant deceptively claimed without scientific support that the risk of addiction could be avoided or managed** a. An Endo-supported publication, titled *Pain Management Dilemmas in Primary Care: Use of Opioids*, recommended screening patients using tools like the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain, and advised that patients at high risk of addiction could safely (*e.g.*, without becoming addicted) receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

	Defendant falsely stated or suggested the concept of "pseudoaddiction" and patients who only need more opioids, and should be treated as such a. Endo distributed copies of a book by KOL Dr. Lynn Webster entitled *Avoiding Opioid Abuse While Managing Pain* (2007). Endo's internal planning documents describe the purpose of distributing this book as to "[i]ncrease the breadth and depth of the Opana ER prescriber base." The book claims that, when faced with signs of aberrant behavior, the doctor should regard it as pseudoaddiction and thus, increasing the dose ***in most cases . . . should be the clinician's first response***." (Emphasis added). b. Endo spent $246,620 to buy copies of FSMB's *Responsible Opioid Prescribing* (2007), which was distributed by Endo's sales force. This book asserted that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of "pseudoaddiction." **Defendant falsely stated or suggested that withdrawal from opioids was not a problem and prescribing or using opioids should be without hesitation** a. A CME sponsored by Endo, titled *Persistent Pain in the Older Adult*, taught that withdrawal symptoms can be avoided entirely by tapering the dose by 10-20% per day for ten days. **Defendant suggested that high-dose opioid therapy was safe** a. Endo sponsored a website, painknowledge.com, through APF and NIPC, which claimed in 2009 that opioids may be increased until "you are on the right dose of medication for your pain," and once that occurs, further dose increases would not occur. Endo funded the site, which was a part of Endo's marketing plan, and tracked visitors to it. b. Endo distributed a patient education pamphlet edited by KOL Dr. Russell Portenoy, titled *Understanding Your Pain: Taking Oral Opioid Analgesics*. In Q&A format, it asked: "If I take the opioid now, will it work later when I really need it?" The response was: "The dose can be increased . . . . You won't 'run out' of pain relief." **Defendant deceptively omitted the risks of opioids, including in comparison to NSAIDs** a. Endo distributed a "case study" to prescribers, titled *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*. The study cites an example, meant to be representative, of a patient "with a massive upper gastrointestinal bleed believed to be related to his protracted use

	of NSAIDs" (over eight years), and recommends treating with opioids instead. b. Endo sponsored a website, painknowledge.com, through APF and NIPC, which contained a flyer called "Pain: Opioid Therapy." This publication included a list of adverse effects from opioids that omitted significant adverse effects like hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death. Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it. c. Endo provided grants to APF to distribute *Exit Wounds* (2009), which omitted warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids. d. Endo sales representatives told prescribers that NSAIDs were more toxic than opioids. On information and belief, these false representations were made to practitioners in the Wallingford area.
Actavis	**Falsehood that scientific evidence supports the long-term use of opioids to improve patients' function and quality of life** a. Documents from a 2010 sales training indicate that Actavis trained its sales force to instruct prescribers that "***most*** chronic benign pain patients do have ***markedly improved ability to function*** when maintained on chronic opioid therapy." (Emphasis added). b. Documents from a 2010 sales training indicate that Actavis trained its sales force that increasing and restoring function is an expected outcome of chronic Kadian therapy, including physical, social, vocational, and recreational function. c. Actavis distributed a product advertisement that claimed that use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and "cause patients to enjoy their lives." The FDA warned Actavis such claims were misleading, writing: "We are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect the drug has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in an overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[95]

[95] Abrams, *supra* at n.66.

	d. Actavis sales representatives told prescribers that prescribing Actavis's opioids would improve their patients' ability to function and improve their quality of life. On information and belief, these false representations were made to practitioners in the Wallingford area. **Defendant misrepresented the risk of addiction** a. Documents from a 2010 sales training indicate that Actavis trained its sales force that long-acting opioids were less likely to produce addiction than short-acting opioids, although there is no evidence that either form of opioid is less addictive or that any opioids can be taken long-term without the risk of addiction. b. Actavis caused a patient education brochure to be distributed in 2007 that claimed addiction is possible, but it is "less likely if you have never had an addiction problem." Although the term "less likely" is not defined, the overall presentation suggests the risk is so low as not to be a worry. c. Kadian sales representatives told prescribers that Kadian was "steady state" and had extended release mechanisms, the implication of which was that it did not produce a rush or euphoric effect, and therefore was less addictive and less likely to be abused. On information and belief, these false representations were made to practitioners in the Wallingford area. d. Kadian sales representatives told prescribers that the contents of Kadian could not be dissolved in water if the capsule was opened, implying that Kadian was less likely to be abused—and thereby less addictive—than other opioids. On information and belief, these deceptive representations were made to practitioners in the Wallingford area. e. In discussions with prescribers, Kadian sales representatives omitted any discussion of addiction risks related to Actavis's drugs. On information and belief, these material omissions were made in presentations to practitioners in the Wallingford area. **Defendant deceptively claimed without scientific support the risk of addiction could be avoided or managed** a. Documents from a 2010 sales training indicate that Actavis trained its sales force that prescribers can use risk screening tools to limit the development of addiction. **Defendant falsely stated or suggested the concept of "pseudoaddiction" and patients who only need more opioids, and**

	should be treated as such a. Documents from a 2010 sales training indicate that Actavis trained its sales force to instruct physicians that aberrant behaviors like self-escalation of doses constituted "pseudoaddiction." **Defendant falsely stated or suggested that withdrawal from opioids was not a problem and prescribing or using opioids should be without hesitation** a. Documents from a 2010 sales training indicate that Actavis trained its sales force that discontinuing opioid therapy can be handled "simply" and that it can be done at home. Actavis sales representative training claimed opioid withdrawal would take only a week, even in addicted patients. **Defendant suggested that high-dose opioid therapy was safe** a. Documents from a 2010 sales training indicate that Actavis trained its sales force that "individualization" of opioid therapy depended on increasing doses "until patient reports adequate analgesia" and to "set dose levels on [the] basis of patient need, not on [a] predetermined maximal dose." Actavis further counseled its sales representatives that the reasons some physicians had for not increasing doses indefinitely were simply a matter of physician "comfort level," which could be overcome or used as a tool to induce them to switch to Actavis's opioid, Kadian. **Defendant deceptively omitted the risks of opioids, including in comparison to NSAIDs** a. Documents from a 2010 sales training indicate that Actavis trained its sales force that the ability to escalate doses during long-term opioid therapy, without hitting a dose ceiling, made opioid use safer than other forms of therapy that had defined maximum doses, such as acetaminophen or NSAIDs. b. Actavis also trained physician-speakers that "maintenance therapy with opioids can be safer than long-term use of other analgesics," including NSAIDs, in older persons. c. Kadian sales representatives told prescribers that NSAIDs were more toxic than opioids. On information and belief, these false representations were made to practitioners in the Wallingford area.
Mallinckrodt	**Defendant Mallinckrodt funded false publications and presentations.**

	a. In 2010, Mallinckrodt sponsored an initiative called "Collaborating and Acting Responsibly to Ensure Safety (C.A.R.E.S.), through which it published and promoted the book "Defeat Chronic Pain Now!" aimed at chronic pain patients. The book is still available for sale and is available online at www.defeatchronicpainnow.com. b. Until at least February 2009, Mallinckrodt provided an educational grant to Pain-Topics.org, a now-defunct website that touted itself as "a noncommercial resource for healthcare professionals, providing open access to clinical news, information, research, and education for a better understanding of evidence-based pain-management practices."[96] Among other content, the website included a handout titled "Oxycodone Safety Handout for Patients," which advised practitioners that: "Patients' fears of opioid addiction should be dispelled."[97] c. In November 2016, Mallinckrodt paid Dr. Scott Gottlieb ("Gottlieb"), the current commissioner of the FDA, $22,500 for a speech in London, shortly after the U.S. presidential election.[98] Gottlieb has also received money from the Healthcare Distribution Alliance ("HDA"), an industry-funded organization that pushes the agenda of large pharmaceutical wholesalers, and he has often criticized efforts aimed at regulating the pharmaceutical opioid market.[99] **Defendant misrepresents the risk of addiction** a. "Defeat Chronic Pain Now!" advises laypeople who are considering taking opioid drugs that "[o]nly rarely does opioid medication cause true addiction."[100] b. "Oxycodone Safety Handout for Patients" included false and misleading statements concerning the risk of addiction associated with

[96] *Pain Treatment Topics*, PAIN-TOPICS.ORG, https://web.archive.org/web/20070104235709/http://www.pain-topics.org:80/ (last visited Dec. 11, 2017).

[97] Lee A. Kral & Stewart B. Leavitt, *Oxycodone Safety Handout for Patients*, PAIN-TOPICS.ORG (June 2007), http://paincommunity.org/blog/wp-content/uploads/ Oxycodone/Handout.pdf.

[98] Lee Fang, *Donald Trump's Pick to Oversee Big Pharma Is Addicted to Opioid-Industry Cash*, Intercept (Apr. 4, 2017, 2:15 PM), https://theintercept.com/ 2017/04/04/scott-gottlieb-opioid/.

[99] *Id.*

[100] Charles E. Argoff & Bradley S. Galer, *supra* n.47.

	prescription opioids: Will you become dependent on or addicted to oxycodone? • After a while, oxycodone causes physical dependence. That is, if you suddenly stop the medication you may experience uncomfortable withdrawal symptoms, such as diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, and other ill feelings. These may take several days to develop. • This is not the same as addiction, a disease involving craving for the drug, loss of control over taking it or compulsive use, and using it despite harm. Addiction to oxycodone in persons without a recent history of alcohol or drug problems is rare.[101] **Defendant deceptively claimed without scientific support that the risk of addiction could be avoided or managed.** a. "Defeat Chronic Pain Now!" states that the issue of tolerance is "overblown," because "[o]nly a minority of chronic pain patients who are taking long-term opioids develop tolerance." In response to a hypothetical question from a chronic back pain patient who expresses a fear of becoming addicted, the book advises that "[i]t is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain." **Defendant falsely stated or suggested the concept of "pseudoaddiction" and patients who only need more opioids, and should be treated as such.** a. The FAQ section of Pain-Topics.org contained the following false and misleading information downplaying the dangers of prescription opioid use: **Pseudoaddiction** – has been used to describe aberrant patient behaviors that may occur when pain is undertreated (AAPM 2001). Although this diagnosis is not supported by rigorous investigation, it has been widely observed that patients with unrelieved pain may

[101] Lee A. Kral & Stewart B. Leavitt, *Oxycodone Safety Handout for Patients*, PAIN-TOPICS.ORG (June 2007), http://paincommunity.org/blog/wp-content/uploads/Oxycodone/Handout.pdf.

	become very focused on obtaining opioid medications, and may be erroneously perceived as "drug seeking." Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated. Along with this, two related phenomena have been described in the literature (Alford, et al. 2006): **Therapeutic dependence** – sometimes patients exhibit what is considered drug-seeking because they fear the reemergence of pain and/or withdrawal symptoms from lack of adequate medication; their ongoing quest for more analgesics is in the hopes of insuring a tolerable level of comfort. **Pseudo-opioid-resistance** – other patients, with adequate pain control, may continue to report pain or exaggerate its presence, as if their opioid analgesics are not working, to prevent reductions in their currently effective doses of medication. Patient anxieties about receiving inadequate pain control can be profound, resulting in demanding or aggressive behaviors that are misunderstood by healthcare practitioners and ultimately detract from the provision of adequate pain relief.[102] **Defendant's document "Commonsense Oxycodone Prescribing & Safety," falsely suggests that generic oxycodone is less prone to abuse and diversion than branded oxycodone: "Anecdotally, it has been observed that generic versions of popularly abused opioids usually are less appealing; persons buying drugs for illicit purposes prefer brand names because they are more recognizable and the generics have a lower value 'on the street,' which also makes them less alluring for drug dealers."[103]** **Defendant misbranded and marketed an unapproved drug** a. On March 30, 2009, Mallinckrodt received a letter from the FDA stating that Mallinckrodt was found to have been marketing an unapproved new drug, morphine sulfate concentrate oral solution 20 mg/ml, in violation of 21 U.S.C. §§331(d) and 355(a). Mallinckrodt

[102] *FAQs*, Pain-Topics.org, https://web.archive.org/web/20070709031530/ ; http://www.paintopics.org:80/faqs/index1.php#tolerance.

[103] Lee A. Kral, PharmD, BCPS, *Commonsense Oxycodone Prescribing & Safety*, PAIN-TOPICS.ORG (June 2007), http://paincommunity.org/blog/wp-content/uploads/OxycodoneRxSafety.pdf.

	had been marketing this unapproved formulation since 2005. The letter also stated that its unapproved morphine formulation was misbranded under 21 U.S.C. §352(f)(1) because the conditions it was intended to treat were not amenable to self-diagnosis and treatment. Adequate directions for such use, therefore, could not be written. As a result, introduction or delivery for introduction into interstate commerce of its unapproved morphine formulation violated 21 U.S.C. §§331(a) and (d).
Insys	**Upon information and belief, defendant sales representatives falsely told prescribers in the Wallingford area that withdrawal from opioids was not a problem and prescribing or using opioids should be without hesitation.** **Upon information and belief, defendant sales representatives falsely told prescribers in the Wallingford area that high-dose opioid therapy was safe, and advocated starting patients at a higher than approved dosage.** **Upon information and belief, defendant sales representatives, in false representations to prescribers in the Wallingford area, deceptively omitted the risks of opioids, including in comparison to NSAIDs** **Defendant created a system of insurance reimbursement to get its prescriptions approved that was based on fraud, such as advising the insurance companies that they were calling from the physician's office or falsely advising the insurance companies that the patient had cancer when (s)he did not.**

D. Unlawful Conduct of Distributor Defendants

319. Under the statutory scheme set out in the Controlled Substances Act ("CSA") enacted by Congress in 1970, wholesale pharmaceutical distributors were given the statutory obligation to have in place "effective controls" to prevent the "diversion" of controlled substances. 21 C.F.R. §1301.71(a). Once a pharmaceutical distributor detects a "suspicious order" of the controlled substance, it is obligated to take several mandatory steps. It must report the "suspicious order" to the DEA. Additionally, the wholesaler must investigate the suspicious order, document the result of the investigation, and, if not reasonably satisfied that the suspicious

order is for the legitimate sale of the controlled substance by the retail pharmacy, hospital, practitioner, mid-level practitioner, or teaching institution ("Retail End User"), it must immediately halt the sale. *See Masters Pharm.*, 861 F.3d at 212-13.

320. Significantly, the Distributor Defendants' aforementioned statutory obligation to monitor and report suspicious orders does not arise solely under the federal CSA. *See* 21 U.S.C. §§801, *et seq.*; Conn. Gen. Stat. §21a-70. Connecticut General Statute §21a-70 requires the registration of all wholesale distributors of controlled substances who distribute into Connecticut, requires that the wholesaler provide control against diversion, and requires that it operate in compliance with any federal, state, and local statute, regulation and ordinance concerning controlled substances. As such, the Distributor Defendants have concurrent duties under both state and federal statutory law to monitor and halt suspicious orders of controlled substances. In addition, the Distributor Defendants have a common law duty that they owe to the Plaintiff, Town of Wallingford, to operate their businesses (the distribution of opioids which are controlled substances) in a lawful, reasonable, and safe manner. This common law duty includes taking reasonable measures to protect the public, and the governmental entity responsible for protecting the public health of its residents, from having the community become awash in an excessive amount of powerful and dangerous opioids.

321. A database known as the "Automation of Reports and Consolidated Orders System" ("ARCOS") was set up under the 1970 Controlled Substances Act. ARCOS is a comprehensive reporting system that shows the flow of every controlled substance from its point of manufacture, through the distributor, and on to the Retail End User.

322. All the Manufacturer Defendants and Distributor Defendants have access to the ARCOS database, and each is under concurrent obligations to enter into the database all transactions with which it is involved for any controlled substance.

323. The ARCOS database is part of the architecture of a "closed system" assuring that every entity that touches a controlled substance is a DEA (and Connecticut) registrant. The Distributor Defendants have been tasked with state and federal statutory obligations to serve as gatekeepers or monitors to ensure that controlled substances are not allowed to flow into a community for illegitimate uses, referred to as "diversion."

324. The ARCOS system shows distribution of controlled substances to Retail End Users on the basis of their zip code. Therefore, one would be able to learn through this database every time that a distributor made a sale to a Retail End User within the zip codes of the Town of Wallingford, or surrounding areas, that appeared to be suspicious, and which specific prescription opioid was shipped.

325. If the Distributor Defendants would permit access to such information, the Plaintiff, Town of Wallingford, could document in this Complaint the gross number of suspicious sales made by each Distributor Defendant to the Town of Wallingford in violation of its statutory obligation.

326. The Distributor Defendants will not permit such access, even in response to a FOIA request. Instead, they require the Government to assert trade secret and confidentiality exemptions under Exemption 4 of FOIA.

327. Three Distributor Defendants, McKesson, Cardinal, and ABC, control 85%-90% of the market share in the United States for the distribution of prescription opioids.

328. It is reasonable to assume, and Plaintiff alleges on information and belief, that the three Distributor Defendants have engaged and continue to be engaged in the unlawful conduct of failing to report suspicious orders, reasonably investigate such orders, or halt such orders, thereby knowingly, recklessly, or negligently making grossly excessive distributions of opioid drugs into the Town of Wallingford, and its surrounding areas, which threatened (and continues to threaten) the public health and safety of residents of the Town.

329. Each Distributor Defendant has repeatedly and purposely breached its duties under state (statutory and common) and federal law with clear knowledge that a foreseeable result of its breach would be the diversion of dangerous prescription opioids for non-medical purposes.

330. On September 26, 2006, the DEA sent a letter to Distributor Defendants McKesson, Cardinal, and ABC cautioning them not to "turn a blind eye to the suspicious circumstances." It further warned that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[104]

331. On December 27, 2007, the DEA sent another letter to Distributor Defendants McKesson, Cardinal, and ABC warning them again of the importance of fulfilling their obligation and their role as gatekeepers for the safe distribution of opioid prescriptions. The DEA letter stated, in part:

> Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent

[104] Letter from Joseph T. Rannazzisi, Deputy Assist. Admin., Office of Diversion Control, to Cardinal Health (Sept. 27, 2006) (a copy of the letter is filed at *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, ECF No. 14-51 (D.D.C. Feb. 10, 2012)).

> analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels.[105]

332. Each Distributor Defendant made the unlawful and unconscionable decision to not halt suspicious sales where it had strong reason to believe, or actually knew, that the prescription drugs were being diverted and not being used for legitimate reasons, thereby subjecting Americans and Connecticut residents, including residents of the Town of Wallingford, to grievous harm up to, and including, death by overdose. Nevertheless, each Distributor Defendant, in derogation of its duty, and with foreseeable harm ensuing to the Plaintiff, continued to permit the sales to go through, for one reason: the sales enhanced the Defendants' profits.

333. Upon information and belief, each Distributor Defendant knowingly made the business decision that payment of whatever fines were imposed was simply the cost of doing business, so long as their unlawful shipments and ensuing profits could continue.

334. Defendant McKesson agreed to pay a $150 million civil penalty to the DOJ on January 17, 2017 for violations of the CSA. Additionally, in 2008, McKesson had agreed to a $13.25 million civil penalty and entered into an administrative agreement for its failure to detect and report suspicious sales. The fine was the result of several district investigations by various DEA field divisions and U.S. Attorneys' offices.

335. The DOJ announced through its Office of Public Affairs in connection with the January 2017 fine to McKesson that, despite entering into the 2008 agreement, "[f]rom 2008

---

105 Letter from Joseph T. Rannazzisi, Deputy Assist. Admin., Office of Diversion Control, to Cardinal Health (Dec. 27, 2007) (a copy of the letter is filed at *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, ECF No. 14-8 (D.D.C. Feb. 10, 2012)).

until 2013, McKesson supplied various U.S. pharmacies an increasing amount of oxycodone and hydrocodone pills, frequently misused products that are part of the current opioid epidemic."[106]

336. In December of 2016, Cardinal agreed to pay $44 million to the DOJ for its violations of the CSA ($34 million for itself and $10 million for a subsidiary).

337. On April 24, 2007, the DEA issued an order to show cause and an immediate suspension order against Defendant ABC's Orlando, Florida distribution center, alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, the DEA suspended ABC's DEA registration at that facility. ABC was allowed to continue shipments of controlled substances from its other facilities, so business was not interrupted.

338. The repeated shipments of suspicious orders, year after year, by each Distributor Defendant, demonstrated its reckless conduct and criminal indifference to its statutory and common law obligations, which it knew would result in a great probability of causing substantial harm to a great many American communities, including the Town of Wallingford.

339. The Distributor Defendants' failure to detect, report, investigate, and halt suspicious orders is a direct, foreseeable, and proximate cause of the diversion of millions of doses of opioids for purposes other than legitimate medical use in the Town of Wallingford.

340. Plaintiff seeks damages from the Distributor Defendants as reimbursement for the costs it incurred, is still incurring, and will for the foreseeable future continue to incur to try to contain and mitigate the hazards to public health and safety caused by the Distributor Defendants. Additionally, Plaintiff seeks injunctive relief, including payment for future costs required to eliminate the public nuisance caused by the Distributor Defendants' unlawful and unconscionable acts.

---

106 *See* Justice News, DOJ, Office of Public Affairs, *supra* at n.5.

E. Defendants Are Estopped from Asserting Statute of Limitations or Laches Defenses

1. The Manufacturer Defendants Fraudulently Concealed Their Misconduct

341. The Manufacturer Defendants, both individually and collectively, made, promoted, and handsomely profited from their misrepresentations and material omissions about the risks and benefits of opioids for chronic pain, even though they knew that their misrepresentations and material omissions were false and deceptive. The long-held medical view, along with research and clinical experience prior to the commencement of the Manufacturer Defendants' campaign of disinformation, established that opioids are highly addictive and responsible for a long list of very serious adverse outcomes. Upon information and belief, the FDA warned Defendants of the questionable basis of chronic long-term use of opioids, and Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and death – all of which clearly described the devastating harm from long-term opioid use. More recently, the FDA and CDC have issued pronouncements, based on medical evidence, that conclusively expose the falsity of Defendants' misrepresentations.

342. Endo and Purdue have recently entered agreements in New York State prohibiting them from making some of the same misrepresentations described in this Complaint.

343. At all times relevant to this Complaint, the Manufacturer Defendants took steps that were designed to and did, in fact, fraudulently conceal their deceptive marketing and unlawful conduct. For example, the Manufacturer Defendants disguised their role in the deceptive marketing of long-term opioid therapy by secretly funding and working through third parties like Front Groups and KOLs. The Manufacturer Defendants never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these

third parties. They did not reveal that CMEs on pain management had been infiltrated by persons that were being paid to espouse the deceptive position of the Manufacturer Defendants that opioids were a safe modality for the treatment of chronic pain, and to suppress the presentation of any other views.

344. The Manufacturer Defendants, other than Insys, ran websites with generic names, such as painknowledge.com, that were actually funded in substantial part by the Manufacturer Defendants.

345. The Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these documents were accurate, truthful, and supported by objective evidence when they were not. For example, the Manufacturer Defendants, other than Insys, distorted the import of the Porter/Jick Letter to the NEW ENGLAND JOURNAL OF MEDICINE (*see supra* at ¶¶159-60). The Manufacturer Defendants, other than Insys, invented "pseudoaddiction" and promoted it to an unsuspecting medical community. (*Supra* at ¶¶152-56). The Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. The Manufacturer Defendants spent tens of millions of dollars over a period of years on a misinformation campaign and so permeated the avenues where information was disseminated to physicians and the medical community that it was difficult, if not impossible, for medical professionals to detect the truth.

346. The Manufacturer Defendants also promoted the false information regarding the relative safety of chronic opioid use directly to the public, especially directing their messages to the elderly and veterans (*supra* at ¶¶250-64). The deception was so widespread that it was difficult for the public to learn the true risk of opioids.

347. Similarly, it was difficult, if not impossible, for Plaintiff to detect the harm being perpetrated on its citizens by the explosive use of opioids for everyday pain. Plaintiff did not and could not have known of the existence or scope of the Manufacturer Defendants' industry-wide fraud and could not have acquired such knowledge through the exercise of reasonable diligence.

2. Distributor Defendants Concealed Their Violations of State Statutory and Common Law as Well as Federal Law

348. Defendants are equitably estopped from relying upon a statute of limitations defense, because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State of Connecticut, and the Town of Wallingford's medical community therein, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws.

349. The Distributor Defendants concealed their unlawful conduct and fraudulently assured the public, the State of Connecticut, and the Town of Wallingford that they were fully compliant with their obligations. For example, a Cardinal Health executive claimed that Cardinal uses "advanced analytics" to monitor its supply chain, and assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[107]

[107] Lenny Bernstein, *et al.*, *How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job'*, WASH. POST (Oct. 22, 2016), https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.30f8a1ea7541.

350. Similarly, McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[108]

351. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Distributor Defendants, through their trade associates, Healthcare Distribution Management Association ("HDMA") and National Association of Chain Drug Stores ("NACDS"), filed an *amicus* brief, which stated:

> Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process.

Masters Pharmaceuticals, Inc. v. U.S. Drug Enforcement Administration, Case No. 15-1335, 2016 WL 1321983, at *25 (D.C. Cir. Apr. 4, 2016) (italics in original). Thus, while acknowledging their duty to report suspicious sales, the Distributor Defendants falsely represented that they acted in compliance with those obligations.

352. The Distributor Defendants have also concealed and prevented discovery of information, including data from the ARCOS database that will confirm the extent of their wrongful and illegal activities. For example, they refused to allow the DEA to reveal the amount of prescription opioids distributed to the Town of Wallingford and the surrounding area by name of distributor and product trade name, claiming trade secret, confidentiality, or privilege, in response to FOIA requests.

---

[108] Scott Higham, *et al*., *Drug industry hired dozens of officials from the DEA as the agency tried to curb opioid abuse*, WASH. POST (Dec. 22, 2016), https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

3. The Statute of Limitations and Laches Doctrine Do Not Apply Here

353. The medical community, patients, their families, the State of Connecticut, and Plaintiff were duped by the Manufacturer Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the State of Connecticut and in the Town of Wallingford.

354. The medical community, patients, their families, the State of Connecticut and Plaintiff were duped by the Distributor Defendants' campaign to misrepresent and conceal the truth that they were dumping opioids into the Town of Wallingford, despite being alerted to the fact that year after year they were ignoring their obligation under state and federal law to protect the community from suspicious sales.

355. All Defendants intended that their actions and omissions would be relied upon, including by Plaintiff. Plaintiff did not know, and did not have the means to know, the truth due to Defendants' actions and omissions.

356. Plaintiff reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

357. The purposes of the statute of limitations period and laches doctrine are satisfied in this case because Defendants cannot claim prejudice where Plaintiff filed suit promptly upon discovering the facts essential to its claims, described herein, which Defendants knowingly concealed. Plaintiff did not and could not have known, through the exercise of reasonable diligence, of its causes of action as a result of Defendants' conduct.

358. Defendants continue their deception to avoid compliance with their legal obligations, by falsely characterizing the opioid epidemics in Plaintiff's community, as well as in the nation, as one of "abuse." In truth, as the Defendants have known for years, the proximate cause of the epidemics is the "use" of opioids – which have been described as "heroin pills" – for

chronic pain, which use was always highly dangerous, medically contraindicated, and likely to cause addiction in exactly the widespread manner in which it has occurred.

359. Plaintiff continues to suffer harm from the public nuisance created by the unlawful actions by the Defendants and, until the nuisance is abated, the harm to the Plaintiff will continue for the foreseeable future.

F. Damages to the Town of Wallingford

360. As a foreseeable, direct and proximate result of the unlawful conduct of the Defendants, along with those of the third-party Front Groups the Defendants assisted and controlled, the Town of Wallingford, along with many other communities in the United States, has been subjected to devastating public health epidemics of addiction and overdoses.

361. As discussed *supra* at ¶¶103-110, it is well-recognized and established biology that, once a person becomes addicted to opioid stimulation of opioid receptors in his or her brain, that person will continue to crave and seek out that stimulation, even if the original prescription drug, which began the addiction, is no longer available either because it is too expensive, or because prescription opioids have become more restricted. The opioid-addicted person will use illicit opioids, such as heroin, or fentanyl, or a combination of those opioids, if they are available. As of 2013, four in five new, street-level heroin users nationally (*i.e.*, 80%) began their opioid addictions through the use of prescription pain medications.[109]

362. As noted above, the Manufacturer and Distributor Defendants, by their misrepresentations, fraud, violations of various statutes, and common law negligence,

---

[109] Pradip K. Muhuri, *et al.*, SAMHSA: CBHSQ Data Review, *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States* (August 2013), https://archive.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf.

orchestrated a scheme to pump millions and millions of "heroin pills" into Connecticut in general and into the Town of Wallingford in particular.

363. But for the misleading information disseminated by Manufacturer Defendants, the prescribers in the Town of Wallingford and surrounding areas would not have begun prescribing opioids as a treatment modality for chronic pain. But for the Distributor Defendants' unlawful conduct under both state and federal statutes, as well as state common law, the amount of opioids flooding the Town of Wallingford and its surrounding areas would not have been so disproportionate to the actual need.

364. As a foreseeable result of increases in opioid drug prescriptions in a community, there follows, as night follows day, increases in overdoses, deaths, and addictions. Additionally, as discussed *supra* at ¶¶111-113, where there is an increase in opioid dependent or addicted persons, there is an increase of persons in the community who are biologically incapable of responding to normal rewards (such as caring for themselves, their family, their schooling, or their job). Moreover, unique among chronic diseases, and directly detrimental to the community, opioid dependent or addicted persons are biologically induced to act in an anti-social manner that may be totally inconsistent with the person's character.

365. Connecticut has been experiencing a heroin overdose outbreak that continues to worsen despite efforts by government officials to bring it under control. For example, in 2012, Connecticut ranked 50th in the nation in terms of opioid deaths, with 2 per 100,000 people. By 2015, however, that number spiked five-and-a-half times, and Connecticut's ranking climbed to 12th,[110] despite a number of legislative actions aimed at curbing the opioid crisis. According to

[110] Brad Drazen, *America's Opioid Crisis is Magnified in Connecticut*, NBCCONNECTICUT.COM (May 18, 2017), http://www.nbcconnecticut.com/troubleshooters/Americas-Opioid-Crisis-is-Magnified-in-Connecticut-422831064.html.

the State's Office of the Chief Medical Examiner, a staggering 917 people in Connecticut died from drug overdoses in 2016, representing a more than 25% jump from 2015 when 729 people died.[111]

366. The State of Connecticut's Department of Mental Health and Addiction Services 2016 Triennial State Substance Abuse Plan states as follows:

> Connecticut has been in the grips of an opioid epidemic that has resulted in increasing numbers of overdose deaths across the state. At the same time, the substance abuse treatment system has seen substantial growth in treatment admissions that are directly related to opioid use. Overdose deaths and an increase in treatment admissions have rapidly intensified over the past three years. This issue has now become perhaps the single most important health concern we as a state are facing.[112]

367. The Town of Wallingford has been significantly impacted by the opioid crisis that is currently devastating Connecticut. According to data from the State's Office of the Chief Medical Examiner, the Town of Wallingford had only 3 opioid-related fatalities in 2012. By 2016 there were 15, constituting a 400% increase.

368. In an effort to save the lives of its residents, the Town has been forced to incur increased costs associated with growing NARCAN administrations. For example, in 2011, the Wallingford Fire Department spent only $200 on NARCAN and $989 on associated operating costs. In 2017, those expenses had increased to $2,431 and $68,539, respectively. In total, the Wallingford Fire Department saw soaring increases in costs related to the purchase and use of NARCAN. Indeed, those total expenses went from $1,189 in 2011 to $70,970 in 2017, a

---

111 Ana Radelat, *Growing number of states press opioid suits against Stamford's Purdue Pharma*, CTMIRROR.ORG (July 6, 2017), https://ctmirror.org/2017/07/06/growing-number-of-states-press-opioid-suits-against-stamfords-purdue-pharma/.

112 *State of Connecticut Dept. of Mental Health and Addiction Services Triennial State Substance Abuse Plan* (2016) at 2, www.ct.gov/dmhas/lib/dmhas/publications/triennialreport2016.pdf.

staggering 5868% increase. Other departments in Wallingford bore similar expenses related to NARCAN administrations. For instance, the Wallingford Health Department spent approximately $1,630 on NARCAN training in 2017 alone.

369. The Town of Wallingford's school system has also been financially impacted by the opioid epidemics. The Town's Health and Wellness Coordinator, as well as the health teachers at the Town's middle and high schools, have been forced to devote a substantial portion of their time to opioid addiction and prevention.

370. Similarly, the Town of Wallingford's Department of Youth Social Services ("YSS") has seen huge expenses for opioid- and addiction-related services in the wake of the Defendants onslaught on the unsuspecting public. For example, YSS incurred costs for the following opioid-related services and programs: public service announcements, salary costs related to drug prevention programs, support groups for the parents and grandparents of opioid addicts, drug prevention programs for teens, and positive youth development program. From July 1, 2009 to March 27, 2018, YSS has incurred approximately $431,000 in opioid-related expenses.

371. Plaintiff has been directly damaged through its payments for chronic opioid therapy (and the frequent ensuing payments for addiction-related treatment) that was unwarranted and potentially dangerous for its employees, retirees, and their families by: (a) partially funding a medical insurance plan for its employees; and (b) its high deductible workers' compensation program.

372. The fact that the Town of Wallingford would pay for such prescriptions was the foreseeable and intended consequence of Manufacturer and Individual Defendants' fraudulent

marketing scheme, and Distributor Defendants' unlawful failure to forestall the bleed of opioids into the Town.

373. In addition to the outright purchases of opioids for its employees, retirees, and their families that the Town of Wallingford has been misled into making, Plaintiff has also been forced to spend extraordinary funds each year in its efforts to combat the public nuisance created by Defendants. Plaintiff has incurred, and continues to incur, costs related to opioid addiction, escalated overdose rates, criminal justice and victimization costs, social costs, lost productivity costs, loss of quality of life, not only for afflicted individuals, but for the families, neighbors, friends, schools and employees. The opioid epidemics proximately caused by the Defendants have devastated the already strained Town. Among other harms (as described herein), the Town has suffered because the resources and funding of the local not-for-profit hospital, community groups, philanthropic groups, social service agencies, and others have been diverted from other projects benefiting the Town, as community groups and Town agencies have come together to try to stem the tide of deaths, broken lives, and the torn fabric of life caused by the proliferation of opioids in the Town of Wallingford.

374. Many of the services that the Town is now forced to provide, oversee, and/or coordinate are not traditionally considered to be municipal services, but have become necessary for the Town to undertake to try to protect its citizens' lives and health and the well-being and sustainability of its community from the devastating effects of the opioid epidemics created and fueled by Defendants.

375. Among the expenditures incurred and the services rendered, which will continue to be needed for the foreseeable future by the Town of Wallingford to try to abate the public nuisance, are the following:

a) costs of purchase and training on NARCAN;

b) transportation costs for transporting patients overdosing from opioids to the hospital and/or coroner's office;

c) increased expenses, and strain on fire, police, EMS personnel;

d) take back unused drug campaigns, outreach to get people with opioid addiction disorders into treatment;

e) implementing prevention programs in the schools;

f) health education programs;

g) programs aimed at alcohol and drug abuse recovery prevention;

h) ongoing public awareness campaigns;

i) diversion programs for drug offenders brought before court

j) overall increase in expenditures for law enforcement and court expenses;

k) rehabilitation clinics, addiction treatment centers, suicide prevention services;

l) services necessary for indigent infants born with prenatal addiction syndrome; and school age children, including foster children, traumatized by addiction in the home;

m) lost productivity of Town employees and consultants who are either suffering from addiction-related medical issues or have a family member suffering from addiction or suffering from traumas of addiction they encounter in their Town jobs;[113]

n) costs for implementing and maintaining new support programs and services to address the opioid crises, including, but not limited to, the Wallingford Coalition for a Better Wallingford;

---

[113] *See* Alan B. Krueger, *Where Have All the Workers Gone? An Inquiry into the Decline of the U.S. Labor Force Participation Rate*, Brookings Papers on Economic Activity, Conference Draft (Aug. 26, 2017), *https://www.brookings.edu/wp-content/uploads/2017/09/1_krueger.pdf*.

o) drug counseling services at the Wallingford Rushford Center;

p) costs associated with the CT Youth Risk Survey Administration and Scoring;

q) negative impact on Plaintiff's workforce, including burn-out rates, increased absenteeism, requests for leave;[114]

r) increased expenses to the Police, Fire, and EMS;

s) Plaintiff's contribution for payments for needless opioid prescriptions prescribed because of Defendants' misrepresentations, for use by Town employees on workers' compensation and Town employees, retirees and family members under Town health insurance plans;

t) coordination with community groups, non-profit organizations, local hospitals implementing "Drug Take-Back Programs," and public dissemination of the risks of opioid addiction, etc.

376. The above list is only illustrative and does not include every category of expense, investment, and necessary services that have been and will continue to be incurred by the Town of Wallingford as a direct and proximate result of Defendants' wrongdoing.

377. The strain to the Town's budget will continue for the foreseeable future and is likely to increase. Additionally, addiction is currently considered to be a brain illness that may be brought into remission, but there is no known cure for that devastating disease. It is also known to be a disease where relapses are common.[115] Accordingly, the damages to the Town of

---

[114] National Safety Council, *How the Prescription Drug Crisis Is Impacting American Employees* (2017).

[115] Thomas R. Kosten, M.D. & Tony P. George, M.D., *The Neurobiology of Opioid Dependence: Implications for Treatment*, SCI PRACT PERSPECT, 2002 July; 1(1): 13-20, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2851054/.

Wallingford have been severe and will continue until the health crisis is abated, which will likely take years, if not decades.

378. Virtually every department within the Town of Wallingford (including the Health Department, Social Services, and Economic Development) has been impacted, and forced to incur additional expenses year after year to try to mitigate the devastating impact of the opioid epidemics to Wallingford's residents.

379. In short, by virtue of the deceptive and fraudulent marketing campaign of the Manufacturer Defendants and the ***wanton and willful violation of their obligations*** by the Distributor Defendants, the Town of Wallingford, the State of Connecticut, and the nation are gripped in the throes of a drug epidemic that is causing substantial economic harm to the Town and its residents.

V. CAUSES OF ACTION

Count I
Public Nuisance
(Against All Defendants)

380. Plaintiff hereby incorporates ¶¶1-379 by reference as if fully set forth herein.

381. The residents of the Town of Wallingford have a common right to be free from conduct that constitutes an unreasonable interference with the public health, safety, peace, and welfare. Defendants, through their conduct described in this complaint, have created a public nuisance that constitutes a significant, unreasonable interference with this common right. Further, this interference is continuing in nature, and has produced a long-lasting effect, and Defendants knew, or had reason to know, the devastating effects their conduct would have upon the Town of Wallingford and its residents.

382. Manufacturer Defendants have intentionally, recklessly, and negligently marketed their opioid products through materially false and misleading statements to physicians,

pharmacists, insurers, and members of the general public that misrepresented the characteristics and safety of opioids and resulted in widespread inappropriate use of these highly addictive and dangerous pharmaceuticals. Distributor Defendants widely disseminated the Manufacturer Defendants' opioid products in the Town of Wallingford in suspicious quantities, in breach of federal law and with knowledge of their likely and foreseeable harm to the residents of Wallingford. Through their promotion, marketing and distribution of opioids for profit, the Defendants created a public nuisance in the Town of Wallingford.

383. Defendants' conduct was unlawful, intentional and reckless and has resulted in significant and unreasonable interference with the public health, safety, peace and welfare of Wallingford residents. As such, Defendants' conduct constitutes a public nuisance and, if unabated, will continue to threaten the health, safety and welfare of the Town's residents. The Town of Wallingford has a clearly ascertainable right to abate conduct that perpetuates this nuisance.

384. Defendants' conduct has substantially and severely injured the public health, safety and welfare of the Town and its residents on many levels, including without limitation, causing death and serious injury, and making many residents of the Town incapable of participating in the labor force, caring for their families, participating in civic life, or leading independent lives.

385. The public nuisance created by Defendants' conduct has directly and proximately caused harm to the Town of Wallingford. The special injuries suffered by the Town as a result of the public nuisance created by Defendants, which are distinct from those to the general public, include expenditures for health services and law enforcement, costs related to opioid addiction

treatment and overdose prevention, and payments by governmental payor programs, such as employee health insurance.

Count II
Violation of the Connecticut Unfair Trade Practices Act (CUTPA),
Conn. Gen. Stat. §42-110a, *et seq.*
(Against the Manufacturer Defendants)

386. Plaintiff hereby incorporates ¶¶1-379 by reference as if fully set forth herein.

387. Manufacturer Defendants violated Conn. Gen. Stat. §42-110b, because, in the conduct of trade or commerce, Manufacturer Defendants have engaged in unfair and deceptive acts and practices.

388. Manufacturer Defendants made, or through their control of third parties, and by aiding and abetting third parties, made and caused to be made, untrue, false, misleading, and deceptive statements of material fact, or made or caused to be made statements that omitted or concealed material facts, rendering the statements misleading, to prescribers, consumers, payors, and Plaintiff, in connection with Defendants' marketing, promotion, sale, and use of prescription opioids. These untrue, false, misleading, and deceptive statements of material fact included, but were not limited to the following:

(a) misstatements relating to the addictive nature of opioids;

(b) misstatements relating to the risk of overdose, death, and irreversible damage to the brain;

(c) misstatements relating to the titration schedules of opioids;

(d) misstatements to the treating physicians, to the medical community in general, to residents of Wallingford, and to the Town of Wallingford relating to the risks and safety of the use of opioids for the treatment of chronic pain;

(e) misstatements relating to and the use of unfair and deceptive practices in connection with KOLs, the creation of false fronts, infiltration of medical societies to perpetuate the Defendants' false message to physicians to peddle their products to masses of persons for whom they were dangerous and caused death or permanent brain damage;

(f) misstatements relating to the viability, risks, benefits, and superiority of alternative treatments;

(g) Purdue's and Endo's false claims that abuse-deterrent opioids reduce tampering and abuse; and

(h) Purdue's false claims that OxyContin provides a full 12 hours of pain relief.

389. Manufacturer Defendants knew, or should have known, at the time of making or disseminating the false statements and material omissions, that they were untrue, false, misleading and deceptive, and therefore likely to deceive the public, the prescribers, the payors, and the Town of Wallingford, about the risks, benefits, and relative superiority or inferiority of opioids.

390. Manufacturer Defendants directly engaged in false, untrue and misleading marketing, and disseminated false, untrue and misleading marketing themselves and through third parties whom they aided and abetted. Manufacturer Defendants made these statements with the intent that the Town of Wallingford and its residents would rely on them, and it was reasonably foreseeable to the Manufacturer Defendants that such reliance would result in the use of opioid prescriptions by persons in quantities and for durations that would cause death or severe harm to users, and harm to the Town. Manufacturer Defendants intended to deceive the

physicians who prescribed opioids to the residents of Wallingford and the payors who purchased, or covered the purchase of, opioids for chronic pain.

391. The Town and its residents did rely on the Defendants' false, misleading and unconscionable statements and the Town of Wallingford has sustained ascertainable losses as a direct and proximate result.

392. Manufacturer Defendants' conduct, as alleged herein, offends public policy, is immoral, unethical, oppressive or unscrupulous, and caused substantial injury to consumers, including the Plaintiff.

393. The Town of Wallingford has suffered an ascertainable loss by reason of Defendants' violation of CUTPA in that, as a direct, foreseeable proximate result of the Manufacturer Defendants' violations, Plaintiff has paid for excessive opioid prescriptions for its current and former employees and their dependents; has paid for healthcare services for the treatment of addiction resulting from their improper opioid treatment; has incurred increased expenditures for police and fire responses triggered by overdoses and suspected overdoses; has incurred increased expenditures for its law enforcement services for families and children, and the homeless, and has been forced to incur the expense of services that the Town of Wallingford never before had to provide, due to the scope and nature of the opioid epidemics.

Count III
Violation of the Connecticut Unfair Trade Practices Act (CUTPA),
Conn. Gen. Stat. §42-110a, *et seq.*
(Against the Distributor Defendants)

394. Plaintiff hereby incorporates ¶¶1-379 by reference as if fully set forth herein.

395. Distributor Defendants violated Conn. Gen. Stat. §42-110b, because, in the conduct of trade or commerce, Distributor Defendants have engaged in unfair and deceptive acts and practices.

396. Distributor Defendants knew or should have known that the distribution of controlled substances must be managed with care to avoid harming the consumer and the public at large through an unwarranted proliferation of the opioids. They knew or should have known that opioid distributions are subject to strict reporting obligations and inventory monitoring in order to detect irregularity in buying patterns relating to the size and frequency of sale of controlled substances, as mandated by relevant state and federal laws and regulations, as well as common sense and common law. Furthermore, Defendants knew or should have known that the buying patterns for opioids grossly deviated from the regular course both in quantity and frequency of purchases, yet failed to report, alert, or otherwise notify authorities of these irregular buying patterns, to investigate or to halt such deliveries.

397. Distributor Defendants knew, or should have known, that their omissions operated to conceal the highly irregular and illegal flow of opioids into the Town of Wallingford. Indeed, Defendants intentionally or purposefully failed to slow down, inspect, report, alert, investigate or halt, or otherwise limit the flow of these dangerous substances into the Town of Wallingford, in order to generate profits that they otherwise would not generate, but for the concealment of the irregular buying patterns. Distributor Defendants knew or should have known that the Town of Wallingford and its residents relied on their non-disclosure of the suspicious sales, and it was reasonably foreseeable to the Distributor Defendants that such reliance would result in the continued and increased use of opioid prescriptions by persons in quantities, frequencies, and durations that would cause death or severe harm to the users and harm to the Town. Distributor Defendants intended to deceive the residents of Wallingford and the payors who purchased, or covered the purchase of, opioids for chronic pain.

398. The Town and its residents did rely on the Distributor Defendants' omissions regarding the illegal and irregular buying patterns, and the Town of Wallingford has sustained ascertainable losses as a direct and proximate result.

399. Distributor Defendants' conduct, as alleged herein, offends public policy, is immoral, unethical, oppressive or unscrupulous, and caused substantial injury to consumers, including the Plaintiff.

400. The Town of Wallingford has suffered an ascertainable loss by reason of Defendants' violation of CUTPA in that, as a direct, foreseeable proximate result of the Manufacturer Defendants' violations, Plaintiff has paid for excessive opioid prescriptions for its current and former employees and their dependents; has paid for healthcare services for the treatment of addiction resulting from their improper opioid treatment; has incurred increased expenditures for police and fire responses triggered by overdoses and suspected overdoses; has incurred increased expenditures for its law enforcement services for families and children, and the homeless, and has been forced to incur the expense of services that the Town of Wallingford never before had to provide, due to the scope and nature of the opioid epidemics.

Count IV
Common Law Fraud
(Against the Manufacturer Defendants)

401. Plaintiff hereby incorporates ¶¶1-379 by reference as if fully set forth herein.

402. Manufacturer Defendants, individually and acting through third parties, made to the Town of Wallingford and its residents untrue, false, misleading, and deceptive statements and omissions of material facts regarding the nature, risks, and benefits of opioids and their use, which statements and omissions Defendants knew were untrue, false, misleading, and deceptive.

403. By making these untrue, false, misleading, and deceptive statements and omissions, Manufacturer Defendants intended that the Town of Wallingford and its residents

would rely on them, and that such reliance would result in the purchase and use of opioid prescriptions in the manner promoted and marketed by Manufacturer Defendants and for Defendants' gain.

404. Defendants' false representations of fact and material omissions of fact had their intended effect in that they caused the Town of Wallingford and its residents to view opioids as a safe and effective treatment for long-term chronic pain, leading to a huge and dangerous increase in opioid usage among Plaintiff's residents.

405. Because Wallingford residents were induced to increase their opioid consumption by Defendants' fraudulent representations of fact and omissions of material fact, the Town of Wallingford suffered actual pecuniary damage. As a result of Defendants' fraud, the Town of Wallingford suffered damages by, *inter alia*, paying for excessive opioid prescriptions for its current and former employees and their dependents; paying for healthcare services for the treatment of addiction resulting from their improper opioid treatment; incurring increased expenditures for police and fire responses triggered by overdoses and suspected overdoses; incurring increased expenditures for its law enforcement services for families and children, and the homeless, and being forced to incur the expense of services that the Town of Wallingford never before had to provide, due to the scope and nature of the opioid epidemics.

406. Defendants' conduct was willful, wanton, and malicious, was directed at the public generally, and intentionally disregarded the rights of the Plaintiff.

Count V
Common Law Fraud
(Against the Distributor Defendants)

407. Plaintiff hereby incorporates ¶¶1-379 by reference as if fully set forth herein.

408. Distributor Defendants knew that buying patterns for opioids grossly deviated from the regular course both in quantity and frequency of purchases in the Town of Wallingford

and its surrounding area, yet failed to report, alert, or otherwise notify any governmental entities, including the Town of Wallingford, of these irregular buying patterns.

409. Distributor Defendants knew at the time of failing to report the suspicious sales that these omissions operated to conceal the highly irregular and illegal flow of opioids into the Town of Wallingford. Distributor Defendants intentionally or purposefully failed to slow down, inspect, report, alert, or otherwise limit the flow of these dangerous substances into the Town of Wallingford in order to generate profits that they otherwise would not generate, but for the concealment of the irregular buying patterns. Distributor Defendants' material omissions of fact had their intended effect in that they caused the Town of Wallingford to remain in the dark regarding the huge and unprecedented increase in opioid pills that Defendants caused to be distributed into their community. As a result of Defendants' wrongful conduct, the Town of Wallingford and its surrounding area became awash in opioid pills, and the Distributor Defendants, as intended, continued to make blockbuster profits.

410. As a direct and foreseeable consequence of the Distributor Defendants' fraudulent omissions, the Town of Wallingford suffered damages by, *inter alia*, paying for excessive opioid prescriptions for its current and former employees and their dependents; paying for healthcare services for the treatment of addiction resulting from their improper opioid treatment; incurring increased expenditures for police and fire responses triggered by overdoses and suspected overdoses; incurring increased expenditures for its law enforcement services for families and children, and the homeless, and being forced to incur the expense of services that the Town of Wallingford never before had to provide, due to the scope and nature of the opioid epidemics.

Count VI
Negligent Misrepresentation
(Against the Manufacturer Defendants)

411. Plaintiff hereby incorporates ¶¶1-379 by reference as if fully set forth herein.

412. The Manufacturer Defendants have failed to exercise reasonable care in the marketing of their opioid products.

413. All Manufacturer Defendants, individually and through third parties, represented that prescription opioids are relatively safe for the management of chronic pain, or made material misrepresentations about the safety of long-term opioid use for chronic pain, when they knew, or should have known, that opioids are highly addictive and have a high risk of overdose, death, or life-long damage to the brain of the person who is administered the drug for a medical indication for which it is not appropriate or for a time period or dosage that is inappropriate.

414. All Manufacturer Defendants made these material misrepresentations and omissions with the intent that the Town of Wallingford and its residents would rely on them, and it was reasonably foreseeable to the Manufacturer Defendants that such reliance would result in the use of opioid prescriptions by persons in quantities and for durations that would cause death or severe harm.

415. The Town and its residents did, in fact, rely on the Manufacturer Defendants' false, misleading and unconscionable statements, and the Town of Wallingford has sustained ascertainable losses as a direct and proximate result. Further, Manufacturer Defendants intended to deceive the physicians who prescribed opioids to the residents of Wallingford and the payors who purchased, or covered the purchase of, opioids for chronic pain.

416. In justifiable reliance on these incorrect statements, which reliance was foreseeable to the Manufacturer Defendants, physicians prescribed opioids for chronic pain, insurers and third-party payors (including Plaintiff) paid for them, and patients took them to devastating effect as described herein. Additionally, the Town incurred expenditures, including, but not limited to:

(a) costs of prescription drugs, including opioids;

(b) costs of governmental payor programs;

(c) health services for the treatment of addiction and overdoses;

(d) increased law enforcement and fire rescue related to overdoses, including costs of administration of Naloxone;

(e) costs for social services, including, but not limited to, addiction prevention programs, and rehabilitation; and

(f) costs of governmental services intended for children, families, youth, and other residents of the Town of Wallingford,

which the Town of Wallingford would not have incurred but for the unfair and deceptive acts and practice of Manufacturer Defendants.

417. Plaintiff has thus been damaged as alleged herein, as a direct and foreseeable consequence of the Manufacturer Defendants' negligent misrepresentations.

Count VII
Negligence
(Against the Distributor Defendants)

418. Plaintiff hereby incorporates ¶¶1-379 by reference as if fully set forth herein.

419. Distributor Defendants knew or should have known that opioid prescriptions are controlled substances and, as such, are subject to strict reporting obligations and inventory monitoring in order to detect irregularity in buying patterns relating to the size and frequency of sale of controlled substances, as mandated by relevant state and federal laws and regulations, common sense and common law. Furthermore, Defendants knew or reasonably should have known that buying patterns for opioids grossly deviated from the regular course both in quantity and frequency of purchases, yet failed to report, alert, or otherwise notify governmental entities or take any action to investigate or stop these irregular buying patterns.

420. Distributor Defendants knew, or reasonably should have known, at the time of failing to report the suspicious sales or take any actions to investigate or stop them, that their omissions operated to conceal the highly irregular and illegal flow of opioids into the Town of Wallingford, and caused an unchecked and dangerous amount of opioid pills to flow into the Town of Wallingford and its surrounding area. Defendants negligently failed to slow down, inspect, report, alert, or otherwise limit the flow of these dangerous substances into the Town of Wallingford.

421. Distributor Defendants knew or should have known that the Town of Wallingford and its residents relied on Distributor Defendants' distributing highly potent opioid pills in a safe and reasonable manner, and that failure to do so would damage the Town and its residents.

422. As a result of Distributor Defendants' negligent non-compliance with their state and federal reporting obligations, and their common law obligations to conduct their business in a safe and reasonable manner, the Town of Wallingford incurred expenditures, including, but not limited to, paying for excessive opioid prescriptions for its current and former employees and their dependents; paying for healthcare services for the treatment of addiction resulting from their improper opioid treatment; incurring increased expenditures for police and fire responses triggered by overdoses and suspected overdoses; incurring increased expenditures for its law enforcement services for families and children, and the homeless, and being forced to incur the expense of services that the Town of Wallingford never before had to provide, due to the scope and nature of the opioid epidemics.

Count VIII
Unjust Enrichment
(Against All Defendants)

423. Plaintiff hereby incorporates ¶¶1-379 by reference as if fully set forth herein.

424. All Defendants received a material benefit from the Town of Wallingford's expenditure of funds for the purchase of opioid prescriptions for its insured employees and retirees under the Town's workers' compensation and medical benefits plans. This material benefit and profit garnered by Defendants from opioid prescriptions purchased and paid for by Plaintiff and its residents was the expected and intended result of Defendants' conscious wrongdoing.

425. At the time the Town of Wallingford made these expenditures, it did so in reliance and under the belief that it was provided with all the necessary and accurate information regarding the risks and benefits of opioid use. The Town of Wallingford relied on the truthfulness and accuracy of Defendants' misrepresentations and omissions to its detriment, because it agreed to confer a benefit on Defendants, which the Town of Wallingford would not have done but for the wrongful conduct of Defendants.

426. Retention of these benefits by each of the Defendants would be unjust.

427. Additionally, it would be inequitable to allow the Town of Wallingford to continue to bear the cost of expenditures it was forced to make to try to support the health and safety of its residents, in the face of the opioid epidemics in its community created by all the Defendants, without shifting the full amount of those expenditures from the Town of Wallingford to the Defendants.

V. PRAYER FOR RELIEF

WHEREFORE, the Plaintiff, Town of Wallingford, demands judgment against each Defendant, jointly and severally, awarding Plaintiff:

1. A finding that by the acts alleged herein, all Defendants violated the Connecticut Unfair Trade Practices Act (CUTPA), Conn. Gen. Stat. §42-11a, *et seq.*;

2. A finding that by the acts alleged herein the Defendants have created a public nuisance;

3. Compensatory damages in an amount sufficient to compensate Plaintiff for all its damages;

4. Punitive damages for the Defendants' fraudulent conduct;

5. An award of all the statutory damages, including punitive damages, pursuant to CUTPA;

6. Disgorgement of the unjust enrichment gained by Defendants as a result of their unlawful conduct;

7. All appropriate injunctive relief necessary to fully abate the public nuisance created by Defendants;

8. Attorneys' fees and costs pursuant to CUTPA; and

9. For all other relief deemed to be appropriate by the Court.

VI. JURY DEMAND

Plaintiff hereby demands a trial by jury.

DATED: April 10, 2018

SCOTT+SCOTT ATTORNEYS AT LAW LLP

David R. Scott (CT 401117)
Margaret Ferron (CT 431445)
156 South Main Street
P.O. Box 192
Colchester, CT 06415
Tel: 860-537-5537
Fax: 860-537-4432

Judith S. Scolnick
Donald A. Broggi
SCOTT+SCOTT ATTORNEYS AT LAW LLP
The Helmsley Building
230 Park Avenue, 17th Floor

New York, NY 10169
Tel: 212-223-6444
Fax: 212-223-6334

Counsel for Plaintiff